UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	)	Hon. Dan A. Polster

Sunday, May 5, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped Deposition of MEREDITH B. ROSENTHAL, Ph.D., VOLUME 2, held at Robins Kaplan LLP, 800 Boylston Street, Suite 2500, Boston, Massachusetts, commencing at 8:04 a.m., on the above date, before Michael E. Miller, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter and Notary Public.

GOLKOW LITIGATION SERVICES
877.370.3377 ph | fax 917.591.5672
deps@golkow.com

Page 478

APPEARANCES:
HAGENS BERMAN SOBOL SHAPIRO LLP
BY: THOMAS M. SOBOL, ESQUIRE
tom@hbsslaw.com
55 Cambridge Parkway
Suite 301
Cambridge, Massachusetts 02142
(617) 482-3700
Counsel for MDL Plaintiffs

BRANSTETTER STRANCH & JENNINGS PLLC
BY: ANTHONY ORLANDI, ESQUIRE
aorlandi@bsjfirm.com
(via teleconference)
TRICIA HERZFELD, ESQUIRE
triciah@bsjfirm.com
(via teleconference)
223 Rosa L. Parks Boulevard
Suite 200
Nashville, Tennessee 37203
(615) 254-8801
Counsel for Tennessee Plaintiffs

KIRKLAND & ELLIS LLP
BY: MARTIN L. ROTH, ESQUIRE
martin.roth@kirkland.com
300 North LaSalle
Chicago, Illinois 60654
(312) 862-2000
Counsel for Allergan Finance LLC

KIRKLAND & ELLIS LLP
BY: CATIE VENTURA, ESQUIRE
catie.ventura@kirkland.com
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
(202) 879-5000
Counsel for Allergan Finance LLC

Page 479

APPEARANCES:
O'MELVENY & MYERS LLP
BY: CHARLES C. LIFLAND, ESQUIRE
clifland@omm.com
MATTHEW KAISER, ESQUIRE
mkaiser@omm.com
400 South Hope Street
18th Floor
Los Angeles, California 90071
(213) 430-6000
Counsel for Janssen Pharmaceuticals Inc.

COVINGTON & BURLING LLP
BY: RONALD G. DOVE, JR., ESQUIRE
rdove@cov.com
850 Tenth Street, NW
Washington, D.C. 20001
(202) 662-5575
Counsel for McKesson Corporation

ROPES & GRAY LLP
BY: NICHOLAS BRADLEY, ESQUIRE
nick.bradley@ropesgray.com
1211 Avenue of the Americas
New York, New York 10036
(212) 256-9000
Counsel for Mallinckrodt
Pharmaceuticals

BARTLIT BECK LLP
BY: PETER B. BENSINGER, JR., ESQUIRE
peter.bensinger@bartlit-beck.com
54 West Hubbard Street
Suite 300
Chicago, Illinois 60654
(312) 494-4400
Counsel for Walgreens Company

Page 480

APPEARANCES:
JONES DAY
BY: STEVEN N. GEISE, ESQUIRE
sngeise@jonesday.com
4655 Executive Drive
Suite 1500
San Diego, California 92121
(858) 314-1200
Counsel for Walmart Corporation

DECHERT LLP
BY: WILL W. SACHSE, ESQUIRE
will.sachse@dechert.com
Cira Centre
2929 Arch Street
Philadelphia, Pennsylvania 19104
(215) 994-4000
Counsel for Purdue Pharma

ARNOLD & PORTER KAYE SCHOLER LLP
BY: SAMUEL N. LONERGAN, ESQUIRE
samuel.lonergan@arnoldporter.com
250 West 55th Street
New York, New York 10019
(212) 836-8000
Counsel for Endo Health Solutions
Inc., Endo Pharmaceuticals Inc., Par
Pharmaceutical, Inc. and Par
Pharmaceutical Companies, Inc.

MORGAN LEWIS & BOCKIUS LLP
BY: WENDY WEST FEINSTEIN, ESQUIRE
wendy.feinstein@morganlewis.com
One Oxford Center
Thirty-Second Floor
Pittsburgh, Pennsylvania 15219
(412) 560-3300
Counsel for Teva Pharmaceuticals
USA Inc., Cephalon Inc., Watson
Laboratories Inc., Actavis LLC, and
Actavis Pharma Inc. f/k/a Watson
Pharma Inc.

Page 481

APPEARANCES:
REED SMITH LLP
BY: LOUIS W. SCHACK, ESQUIRE
lschack@reedsmith.com
1717 Arch Street
Suite 3100
Philadelphia, Pennsylvania 19103
(215) 851-8100
Counsel for AmerisourceBergen Drug
Corporation

WILLIAMS & CONNOLLY LLP
BY: CARL R. METZ, ESQUIRE
cmetz@wc.com
725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000
Counsel for Cardinal Health Inc.

MORGAN LEWIS & BOCKIUS LLP
BY: AJANI BROWN, ESQUIRE
ajani.brown@morganlewis.com
(via teleconference)
1000 Louisiana Street
Suite 4000
Houston, Texas 77002
(713) 890-5000
Counsel for Rite Aid

LOCKE LORD LLP
BY: MADELEINE E. BRUNNER, ESQUIRE
maddie.brunner@lockelord.com
(via teleconference)
2200 Ross Avenue
Suite 2200
Dallas, Texas 75201
(214) 740-8000
Counsel for Henry Schein, Inc. and
Henry Schein Medical Systems, Inc.

A P P E A R A N C E S:
MARCUS & SHAPIRA LLP
BY: RICHARD I. HALPERN, ESQUIRE
halpern@marcus-shapira.com
(via teleconference)
One Oxford Centre
35th Floor
Pittsburgh, Pennsylvania 15219
(412) 471-3490
Counsel for HBC Services

FOLEY & LARDNER LLP
BY: KRISTINA J. MATIC, ESQUIRE
kmatic@foley.com
(via teleconference)
777 East Wisconsin Avenue
Milwaukee, Wisconsin 53202
(414) 271-2400
Counsel for Anda Inc.

ALSO PRESENT:
FORREST MCCLUER, Ph.D.
Greylock McKinnon Associates
(via teleconference)

VIDEOGRAPHER:

VINCENT ROSICA,
Golkow Litigation Technologies

INDEX

APPEARANCES 478

PROCEEDINGS 485

EXAMINATION OF MEREDITH B. ROSENTHAL, Ph.D.:

BY MR. METZ 746

BY MR. GEISE 843

BY MR. SOBOL 845

CERTIFICATE 847

ERRATA 849

ACKNOWLEDGMENT OF DEPONENT 850

LAWYER'S NOTES 851

DEPOSITION EXHIBITS
MEREDITH B. ROSENTHAL, Ph.D.
May 5, 2019

NUMBER	DESCRIPTION	PAGE
Rosenthal-22	Data Appendix	553
Rosenthal-23	Case and Deaton Publication	599
Rosenthal-24	CDC Guideline for Prescribing Opioids for Chronic Pain, United States, 2016	650
Rosenthal-25	2017 Haider et al Publication	689
Rosenthal-26	AAEM White Paper on Acute Pain Management in the Emergency Department	703
Rosenthal-27	MD Anderson Cancer Center Postoperative Pain Management Guidelines	710
Rosenthal-28	Kadian Instructions for Use	726
Rosenthal-29	Joint Statement, Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act	809
Rosenthal-30	State of Ohio House Bill No. 187	825
Rosenthal-31	Ohio Prescription Drug Abuse Task Force Final Report	834

PROCEEDINGS

(May 5, 2019 at 8:04 a.m.)

THE VIDEOGRAPHER: We're now on record. My name is Vince Rosica. I'm a videographer for Golkow Litigation Services. Today's date is May 5th, 2019, and the time is 8:04 a.m.

This video deposition is being held in Boston, Massachusetts in the matter of National Prescription Opiate Litigation, MDL No. 2804 for the Northern District of Ohio, Eastern Division Court.

The deponent is Meredith Rosenthal.

Counsel will be noted on the stenographic report.

The court reporter is Mike Miller and will now swear in the witness.

(Witness sworn.)

MR. SOBOL: Before you begin, I think the professor had one quick update.

THE WITNESS: Yes. Remember

Page 486

yesterday you were asking me about if I had testified in other litigation related to opioids, and I knew that I had been retained in a case, and I could not remember whether I had actually testified. So I looked that up, and indeed, sometime around five years ago, not recently enough to appear in the case captions that I list at the back of my CV, I testified in a matter related to Actiq, the Cephalon drug.

MR. ROTH: You anticipated my very first question.

THE WITNESS: Excellent.

MEREDITH B. ROSENTHAL, Ph.D., having been previously duly sworn, testified as follows:

BY MR. ROTH:

Q. What was the nature of your expert opinion in that case?

A. I did a damages analysis for class certification proceedings.

Q. And was it limited to a single manufacturer?

Page 487

A. Yes, it was a single drug, single manufacturer. I can't recall the details. I didn't go all the way back to the complaint, but it was an off-label marketing case.

Q. And do you recall whether you used a regression analysis in that case?

A. I did not.

Q. Okay. May have more questions, but that's good for now.

Professor Rosenthal, you mentioned a couple of times yesterday that you excluded injectables from your analysis?

A. Yes, that's right.

Q. Why did you do that?

A. That was in consultation with counsel. So I understood they were not to be considered in the matter, and I understand from clinical experts that the uses of the injectables are somewhat different than the orals.

Q. Do you know anything about whether the marketing for injectables differs from the marketing for the oral opioids?

A. I do not.

Page 488

Q. Your model does not attribute any causality to manufacturers based on alleged deficiencies in the suspicious order monitoring regime?

A. My assignment was to examine the impact of the allegations with regard to marketing, and so I have not specifically looked at the impact of any monitoring-related allegations.

Q. And that would be true also for the distributors and the pharmacies; because your allegations relate to marketing, you have not included them in any of your analyses in your reports?

MR. SOBOL: Objection.

A. Again, my assignment was to examine the impact of the alleged unlawful marketing. I have not considered other conduct in my analysis.

BY MR. ROTH:

Q. We spoke yesterday about endogeneity, and I think I marked as Exhibit 14 an article you wrote for the Kaiser Family Foundation, if you could pull that up, please.

Page 489

A. Let me see if Mike organized my documents. Yes. Go ahead.

Q. You testified yesterday that endogeneity did not need to be controlled for in your model because it's an aggregate model.

A. Yes.

Q. Are you aware of any economic literature that does control for endogeneity in an aggregate model measuring the impact of promotion on sales?

A. An industrywide aggregate model like mine, I'm not aware of one.

Q. And is there a difference in your mind between industrywide versus classwide?

A. Yes, there is. Again, if the notion is that whatever causes the endogeneity has to be either some kind of simultaneous decision-making around price and quantity, for example, or a feedback loop, and at the level of the industry, that's simply not plausible, that the industry is coordinating its marketing in that way.

Q. Your model in this case though

Page 490

is not actually an industrywide model, is it?
A. Again, industrywide for the opioid industry?
Q. Well, except you take out all of the non-defendants from your model?
A. Well, that's not true. The model is all of the -- all of the opioids. The but-for scenario takes -- leaves the non-defendants as they were, but the model concludes all of them.
Q. Right. So in the but-for scenario where you take out the non-defendants, what did you do to compare their promotional activities to the defendants' promotional activities?
MR. SOBOL: Objection.
A. Well, such a comparison is not part of the overall analysis. Again, we've talked about the Table C, which presents the marketing by defendants and non-defendants, so the data are in there.
The model itself includes marketing for all opioids, and the but-for scenario simply disaggregates and identifies as a part of that process the marketing of

Page 491

non-defendants, but it does so only to generate different predictions of what sales would have been, so there -- I did not make a statistical comparison between non-defendant and defendant promotion.
BY MR. ROTH:
Q. When you removed the non-defendants, what did you do to confirm that that did not take out, for example, the non-rivalrous marketing and leave you with a set of just the rivalrous marketing?
MR. SOBOL: Objection.
A. What I'm examining in my aggregate model is the net effect, rivalrous market expanding of promotion, and so the model calculates that average market expansion effect and essentially all of the rivalrous marketing, it nets out by definition because to the extent that we're talking about rivalrous marketing as defined as moving market shares from one drug to the other, which is basically the definition of rivalrous marketing, all the pluses have to net out with the minuses.
And so that -- that does not

Page 492

appear in the output of my model because it's not relevant to my assignment. So by taking out all of the -- actually, technically, it's sort of a double negative. I actually leave in all of the non-defendant promotion in the but-for scenario because it would have happened regardless of whether the allegations are true or not.
By leaving that in, if it has rivalrous components to it, if it has market expanding components to it, whatever that is will show up in my predictions.
BY MR. ROTH:
Q. Yeah. What I'm trying to understand is I think we agree that when you look at an individual manufacturer there could be endogeneity issues in the form of price or in the form of detailing physicians who are predisposed to prescribe their product?
A. If we were looking at an individual manufacturer, we could have some of those endogeneity concerns, but I do not look at an individual manufacturer.
Q. I understand that.

Page 493

Even if we look at a group of manufacturers, we would still have endogeneity concerns to a degree?
MR. SOBOL: Objection. Excuse me. Asked and answered.
A. It's my opinion that in this -- when we're looking at the level of the entire opioid industry, that the conceptual basis for such endogeneity concerns is really not there, and even -- even if at the second stage of my analysis I parse out some subset of defendant, of manufacturers, sorry, non-defendants, in particular, that in and of itself doesn't raise a new endogeneity concern. The model is estimated on the marketwide effects.
BY MR. ROTH:
Q. I'm trying to figure out where the line is though. So like how many manufacturers need to be included for all of the endogeneity and rivalrous marketing issues to just net out and show market expansion as opposed to the effects of just the subset you're looking at?
MR. SOBOL: Objection to the

Page 494

form.
You can answer.
A. The rivalrous marketing will always net out. Again, it's just mathematically true that by definition, marketing that only moves market share, it has to net out. So that's just an identity.
That will always be true when we look at any subgroup of products that we -- that the rivalrous piece will net out. It just has to.
BY MR. ROTH:
Q. What about endogeneity?
A. The endogeneity issue in my opinion is where we have the entire opioid class in the analysis. It does not make sense to think about this month-to-month reverse causality for marketing as a whole for the industry, relative to sales as a whole for the industry. It's not how individual companies set their marketing budgets.
It just doesn't make economic sense to me, so for the analysis at hand, looking at the entire opioid industry, I do

Page 495

not believe that there's a conceptual basis for the same endogeneity concerns that we might have with an individual drug or an individual company.
Q. Your analysis compares your industrywide but-for scenario against a scenario with just the defendant manufacturers, correct?
MR. SOBOL: Objection.
A. So my analysis ultimately compares the predicted -- the actual predicted sales, so that's leaving everything the same with a world in which we pull out some subset of the marketing.
BY MR. ROTH:
Q. So what I'm trying to understand is I understand your position on the big but-for scenario with the whole industry, but why is endogeneity not a concern for the pulled-out set of manufacturers?
MR. SOBOL: Objection.
A. There's no estimation that's going on there, so endogeneity is a concern when we're estimating parameters using a

Page 496

regression model. It is not -- the second stage of my analysis is simply employing those parameters to predict a different scenario, and so endogeneity, it's -- it's not a relevant construct for that prediction piece.
BY MR. ROTH:
Q. If you look at Exhibit 14, this was the article you prepared for the Kaiser Family Foundation in 2003, and if you look at page 2, the last paragraph on the page, you say: In this paper, we examine the effects of two types of promotional spending for brands in five therapeutic classes of drugs, using monthly aggregate data from August 1996 through December 1999.
Do you see that?
A. I do.
Q. So you actually looked at five different classes of drugs. Do you recall what drugs they were?
A. Antidepressants, nasal sprays, nonsedating antihistamines, PPI's, which are proton pump inhibitors, and number 5, let me just look at -- there are some tables that

Page 497

are probably the easiest place. I'm blanking on the fifth one. Cholesterol, anticholesterol drugs.
Q. Turn to page 14, please.
A. Okay.
Q. And on page 14 you say: We take account of the possibility that spending on direct-to-consumer advertising and physician promotion and product sales are jointly determined by estimating instrumental variables, IV, models where all three variables are assumed to be endogenous.
Do you see that?
A. Yes.
Q. And I think you said yesterday this article only solved for endogeneity at the product level?
A. I believe so, yes.
Q. Okay. And if you look at the bottom of page 9, in the last paragraph it says: At the top level of the tree, which represents the therapeutic class of drugs, we estimate the impact of DTCA spending and detailing in the context of a Cobb-Douglas demand specification, double logarithmic. In

Page 498

the analysis of competition at the individual product level within each class we specify and estimate three alternative models: 1, an AIDS-type specification; 2, a logit model with log of quantity share divided by, one minus quantity share, on the left-hand side, and prices and promotional spending on the right-hand side; and 3, a Cobb-Douglas model in log levels.

Do you see that?

A. Yes, I do.

Q. And then on page 15, under Econometric Results, it says: We begin by presenting results in Table 3 for the top of the tree structure in Figure 2, the class level quantity equations.

Do you see that?

A. I do.

Q. And then if you look at Table 3, which is on page 25, the top two lines say: Class DTC and Class Detail, and they have an asterisk that says Endogenous, IV Estimated.

Do you see that?

A. Yes, I do. Actually, I can

Page 499

keep reading, but I think essentially the class level estimates are the sum of the individual product level estimates. So again, the instrumentation was at a product level.

Q. And then applied to the class level through aggregation?

A. That's right.

Q. Okay. And if you had disaggregated individual drugs or manufacturers in this case, you could have applied an instrumental variables method to each and aggregated them similarly here?

MR. SOBOL: This case, the opioids case, not this?

MR. ROTH: Correct, so let me reask it.

MR. SOBOL: Yeah.

BY MR. ROTH:

Q. If you had used disaggregated individual drugs or manufacturers in the opioids case we're talking about now, you could have applied an instrumental variables model to each individual drug and then aggregated them as you did in this article?

Page 500

A. Unlike the research question in this paper, my assignment asks me to compute the impact of the alleged misconduct at the level of the class, the industry, opioid industry as a whole. And so it was not appropriate for me to look at individual drug level analyses.

I maintain that at that class level, industry level, these endogeneity questions do not pertain.

Q. Did you test that hypothesis by looking at an individual defendant or two to see how the issues there compare to how your model handles endogeneity?

A. Since my assignment was an aggregate assignment, I have conducted my analysis at the aggregate level. I have not conducted my analysis at the level of an individual defendant.

Q. And, in fact, to confirm, you've not reviewed any individual defendant's marketing materials for any drug at issue in this case?

MR. SOBOL: Objection, asked and answered.

Page 501

A. I'm not sure what you mean by that exactly. I reviewed the documents that you see I relied on in my report. I would consider those to be marketing materials.

BY MR. ROTH:

Q. You've not reviewed any manufacturer's marketing plan for any drug at issue in this case?

MR. SOBOL: Objection.

A. Again, I'm not sure that that's entirely correct. I do cite to what I would consider to be marketing plans.

BY MR. ROTH:

Q. Okay. Aside from the documents reflected in Attachment B or cited in your report, you've not reviewed any marketing materials for any drugs at issue in this case?

A. Aside from materials cited in my report, I've certainly not relied on any of those marketing materials.

Q. And aside from the depositions reflected in Attachment B, you've not reviewed any depositions from any manufacturer's sales representatives?

Page 502

A. Aside from the depositions that I cite in my report, I'm not relying on any other deposition testimony, no.
Q. You've not reviewed any testimony or other direct evidence from doctors about how they were affected by a given manufacturer's promotion?
MR. SOBOL: Objection.
A. As I note in my report, as an economist, asked to examine the impact of the alleged marketing misconduct, interviewing physicians would not be a scientifically appropriate methodology to ascertain impact.
We know that self-report is unreliable, particularly when it comes to behavior that may be socially unacceptable.
BY MR. ROTH:
Q. So if doctors from Summit or Cuyahoga County testified at trial that they were detailed but it didn't affect them, as an economist, you would dismiss that testimony?
MR. SOBOL: Objection.
A. As an economist, I would rely on the evidence about what people do and not

Page 503

what people say. It's been demonstrated in the literature, literature that I cite in my report, that again, that self-report is not a reliable basis for ascertaining impact, so I would not rely on physician self-report.
BY MR. ROTH:
Q. If defendants presented testimony from 15 doctors at trial who all said their prescribing practices were unaffected by opioids promotion, would your position be different?
A. I do not believe that numeracy overcomes bias. There's no scientific basis for such a conclusion, so no, I do not believe that physician self-report is reliable, even if there are 15 physicians.
Q. So in your view as an economist, the testimony of any number of doctors regarding how they viewed the effect of defendants' promotion has no relevance?
A. I would not draw any conclusion from such testimony for the purposes that my report has been set forth.
Q. You did not review any manufacturer's disaggregated marketing data

Page 504

for the purpose of your analysis?
MR. SOBOL: Objection, form.
A. Again, in my report I cite certain documents that have data in them related to marketing. I do not use those data in my calculations.
BY MR. ROTH:
Q. And I think you said yesterday, you made a very specific request to look for such data. Do you remember that?
A. I did, yes.
Q. And why did you ask for that?
A. When I started my work, I wanted to know about what all the possible data sources that would be available were.
Q. And if you had a more robust source of disaggregated marketing data across defendants, would you have used that to model promotion instead of the IQVIA data that you used?
MR. SOBOL: Objection.
A. I can't say for sure, but I wanted to find all the data that I could from -- from discovery.
///

Page 505

BY MR. ROTH:
Q. You did not review any manufacturer's detailing call notes?
A. I did not review any detailing call notes, no.
Q. And I think you said this yesterday, but just to confirm, you did not comprehensively review all of any given manufacturer's marketing budgets for a specific drug in this case?
MR. SOBOL: Objection, asked and answered.
A. I did not systematically review those marketing budgets, no.
BY MR. ROTH:
Q. And so when you calculate the percentages in Table 3 of your report, as we discussed, that's just a comparison of removing each defendant's promotional contacts in the data from the aggregate model?
MR. SOBOL: Objection, asked and answered.
A. Table 3 presents alternative simulations of but-for scenarios in effect,

Page 506

in which individual defendants are -- their marketing efforts are deemed to be not subject to recovery of any kind, and so that those marketing efforts are left in the but-for scenario.

So it is a -- it's a product of the regression -- my direct regression model.

BY MR. ROTH:

Q. I want to work with you on a hypothetical. So let's assume that no opioid marketing occurred beginning in 1993.

A. No opiate -- opioid marketing at all?

Q. Correct, no promotion, no IQVIA contacts.

A. Okay.

Q. So in your model --

MR. SOBOL: I'm sorry, just so it's clear, do you mean that or the broader --

MR. ROTH: Well, let's start with -- that's fair.

MR. SOBOL: You know what I mean?

MR. ROTH: That's fair.

Page 507

BY MR. ROTH:

Q. So let's start with no promotion at all, no marketing, no detailing, no articles, nothing, a world without promotion, okay?

A. Okay.

MR. SOBOL: Sounds wonderful.

BY MR. ROTH:

Q. All right. So if promotion hadn't occurred since 1993, the only thing your model would use would be price and the constant terms.

MR. SOBOL: Objection.

But you can answer.

BY MR. ROTH:

Q. Correct?

A. You're sort of suggesting that the underlying data would be totally different, but yes, the -- if the stock of promotion is always zero, then it wouldn't enter into the estimation, so it would be price and the constant term, yes.

Q. What does your model say the level of sales would be if the stock of promotion is always set to zero?

Page 508

A. Well, again, you're constructing a hypothetical that's outside of the world in which I'm actually putting this model together, but it would depend on the level of sales.

Essentially, as you can see in my indirect model, price would cause a small decline in sales over the time period.

Q. So would it show any sales?

A. Well, your hypothetical is -- you didn't tell me what the baseline level of sales was.

Q. Okay. So assume a small baseline level of sales. It would start there and decline over time? Is that what you're saying?

A. Yes.

Q. Okay. So -- and the reason for that is because all of the sales in your model are explained by marketing as counterbalanced by price?

A. Well, again, you have to take into account the specifics of the specification I used. So the sales are explained by marketing in combination with

Page 509

the depreciation rate in combination with the specific functional form I use.

Your hypothetical is not one that makes any sense to me as a health economist, and it's generally good practice in applied economic analysis to not extrapolate too far outside of the world you're analyzing. So we don't want to forecast 50 years out from this model.

Likewise, to apply it to a world in which there's no marketing when that is so different from the world that we're in, is -- it's a stretch that doesn't make a lot of sense to me as a hypothetical.

Q. But in order to test whether your model allows for anything but marketing to cause sales, does it not make sense to set marketing at zero?

A. It does not make sense to me to set marketing at zero. That's not something I would do in a model like this.

Q. All right. If we do set marketing to zero, however, it shows that no other factors are driving an increase in sales in your model?

Page 510

A. In the model, if -- if promotion were at zero, Model C might look different. In fact, promotion is the dominant factor driving sales, so what you're asking is a hypothetical that essentially assumes away what we know the fundamental sales driver is in this industry, and so it's a nonsensical hypothetical to me.

Q. And when you say you know the fundamental sales driver for opioids is marketing, how do you know that?

A. Look at Dr. Perri's report. Look at any of the articles that we've talked about. Promotion is critically important in the pharmaceutical industry.

Q. That's an assumption you're making based on Dr. Perri, not something that you've studied specifically in the opioid industry before, correct?

MR. SOBOL: Objection. Objection, asked and answered.

A. That's -- it's based on economic theory. It's based on economic and marketing analysis. It's not an assumption that I'm just taking from Dr. Perri.

Page 511

BY MR. ROTH:

Q. So in your view, a model that allows for nothing but promotion to predict positive sales is reasonable because you believe promotion is what drives marketing for opioids?

MR. SOBOL: Objection.

MR. ROTH: Sorry, that was a bad question. Let me rephrase it.

BY MR. ROTH:

Q. In your view, a model that allows for nothing but promotion to predict positive sales is reasonable because you believe promotion is what drives sales for opioids?

MR. SOBOL: Objection.

A. I think there are many issues I would have with that statement. So, first of all, my model is looking at the extent to which promotion is driving increases in sales.

As we talked about at length yesterday, there may be things that affect whether a particular patient or a particular physician uses a specific medicine. What I'm trying to explain is growth over time, so that's not the same as what might explain levels.

Second, I would say that the model demonstrates that promotion causes sales. It is not an inherent assumption. The basic structure of my model is the same as the models in the published papers that we looked at that use aggregate time series data because in time series, we're looking at the factors that drive changes over time, and prices and promotion are those factors.

BY MR. ROTH:

Q. In your view, your model proves the hypothesis that promotion of opioids drives increased sales of opioids?

A. Yes, that is the conclusion I reach in my report.

Q. And before you put your regression model together, you believed that promotion of opioids drove sales of opioids?

A. As a health economist and as someone who's done work in this area before, my priors were that promotion is an important factor in causing sales increases, yes.

Page 513

Q. And, in fact, nothing aside from promotion in your model would allow for an increase in the sales of opioids?

MR. SOBOL: Objection.

A. In setting up the model, before doing the analysis, while I expected prices to have the relationship with sales that they did, I did not know whether the prices, as we discussed yesterday, would be rising or falling.

So as a matter of specifying the model, the effect of prices could have been either to accelerate or decelerate growth.

BY MR. ROTH:

Q. That was a good answer, but I don't think it directly responded to my question.

In your model --

MR. SOBOL: That's a contradiction.

BY MR. ROTH:

Q. In your model, there is nothing aside from increased promotion that causes an increase in the sale of opioids?

Page 514

MR. SOBOL: Objection, asked and answered.
A. Again, in the model as specified, prices could have had either a positive or negative effect, not because the coefficient could have been positive or negative, but because the trend could have been positive or negative.
In practice, when I estimated the model, the underlying data suggested that prices were, in fact, increasing, and thus decreasing sales, and so promotion is the single variable in Model B that is causing increases in sales.
In Model C, as we talked about yesterday, one of the dummy variables appears positive in a way that is counterintuitive; nonetheless, it accounts for some of that sales growth.
BY MR. ROTH:
Q. You included no other variables in your direct regression model beyond price and promotion; is that right?
A. In Model B, I include price, promotion, the constant, and I estimate the

Page 515

depreciation rate.
In Model C, I include those five event dummies.
Q. What did you do to measure the impact of non-defendant promotion on market expansion?
MR. SOBOL: Objection, asked and answered.
A. My model is an aggregate model and the estimation includes defendants and non-defendants, and so the coefficient estimated on promotion in the model pertains to the impact of both defendants and non-defendants.
BY MR. ROTH:
Q. Your but-for world in your model excludes defendant promotion?
A. The but-for scenario excludes defendant promotion, yes.
Q. What is the result if the but-for world excludes all promotion and keeps all else equal?
A. I have not been asked to look at a but-for scenario. As we were talking before about the idea of zero promotion,

Page 516

that's not a scenario I've looked at.
Q. You spoke a minute ago about Model C. I want to come back to that for a minute.
If you turn to Table 1.
A. 47.
Q. Thank you.
A. Mine is getting well leafed.
Q. And actually, that's not the one I want. I'm sorry. I went the wrong way. I actually want Attachment D, the table that shows your coefficients for Model C.
A. Okay.
Q. So I think it's D.8.
A. No.
Q. No, D.8. Table D.8.
A. Oh, Table D.8, sorry.
Q. Yeah. You numbered the tables the same way as the pages. It makes it confusing.
A. Very confusing, okay.
Q. So in Table D.8, the stock of promotion with the trend for the period starting in August 10 is negative; is that right?

Page 517

A. That's right.
Q. And you maintain the negative depreciation rate, which means sort of growing stock of promotion even in that period?
A. Right.
Q. And we spoke about that a little bit yesterday, but can you just explain for me why it is that the effectiveness of promotion as a whole is declining but the stock of promotion continues to grow in the third period of your model?
MR. SOBOL: Asked and answered.
You can answer.
A. Yes. The depreciation rate, I estimate a single depreciation rate over the entire time period, and it's my belief that the negative depreciation rate reflects the addictive nature of opioids.
That does not change in the latter part of the period, so despite the fact that the marginal productivity of promotion is declining over that period, the idea that the stock of promotion continues to

Page 518

grow is not conceptually inconsistent.
BY MR. ROTH:
Q. We agree that all detailing is not equally effective?
MR. SOBOL: Objection.
A. I -- here I am trying to estimate -- I am estimating the average effect of detailing. There may be some variation in that effect, but I'm interested in the aggregate impact.
And so the fact that my analysis averages across some -- some variation is not mathematically a problem. It will still lead me to the right answer in terms of the aggregate impact.
BY MR. ROTH:
Q. I assume you agree based on the way you've constructed Model B that the effectiveness of detailing changes over time?
A. That is what Model B captures.
Q. Right. Detailing that may have been effective earlier in time may become less effective over time as new information comes to light?
A. Well, I think the premise

Page 519

you're suggesting there is, again, it ignores the addictive nature of the product, so once a patient is using opioids and has increasing needs for higher doses; whether or not the specific messages are still in the mind of their physician, they are nonetheless addicted to the product or tolerant of the product and requiring higher and higher doses which will show up in my data as higher and higher MMEs.
So I can't quite agree with the premise and its relevance to the analysis.
Q. Based on your last answer, I assume you'd agree that when a patient receives higher doses of opioids, that may be a sign of tolerance as opposed to addiction?
A. Yes, higher doses may be tolerance and not necessarily addiction. Again, I'm not a clinical expert, so I want to be careful not to go too far with that.
Q. In fact, a patient who is being successfully treated with opioids for chronic pain may become tolerant and need a higher dose to achieve the same pain deterrent effect?

Page 520

A. I think we're getting a little too far out of my expertise and into clinical questions.
Q. Do you believe that promotion has a greater impact on the very first prescription a physician writes for a therapy like opioids or for subsequent prescriptions the physician may write for the same drug?
MR. SOBOL: Objection.
A. I'm not sure it makes conceptual sense to distinguish that. I think that there is a -- there is an inherent connection that happens when someone starts on a medicine. They have a higher probability of being on that medicine next month than someone who didn't start, right, so that -- that would be a natural underlying connection between the two things.
It may be that promotion also has a reminder effect, and so that would be an increment in addition to the fact of that patients once on a drug may be likely to stay on a drug.
I have not tried to distinguish those factors.

Page 521

BY MR. ROTH:
Q. Is that an issue that you have studied or seen economic literature on, whether promotion is more effective at getting doctors to initiate a therapy versus maintain a therapy they've already used in the past?
A. Again, for the purposes of my analysis, I had no need or wish to distinguish between those things. I can't point to a paper right now, but I believe that maybe someone has done that.
Q. I assume you're aware there are different classes of opioids, correct?
A. There are different molecules, like oxycodone and hydrocodone, is that what you're referring to when you say classes?
Q. Well, there are different molecules, that's one thing.
A. Yes.
Q. There are different formulations, right?
A. Yes.
Q. There are different methods of administration?

Page 522

A. Yes.
Q. There's a patch, right?
A. Yes.
Q. There's that sublingual spray?
A. Yes.
Q. And then there's pills and injectables, for example?
A. Yes.
MR. SOBOL: Film.
BY MR. ROTH:
Q. Film?
A. Yes, I'm aware that there are different formulations.
Q. And there's also immediate-release opioids and extended-release opioids, correct?
A. Yes, that's correct.
Q. And for the purpose of your models, apart from the injectables, all of those various forms of opioids are included?
A. Yes, that's correct.
Q. Did the manufacturers' marketing budgets that you reviewed show increased marketing spending over time?
A. As I sit here, I don't recall.

Page 523

Q. Would you agree that if the depreciation rate augments the stock of detailing over time, it would be irrational to keep spending money on promotion?
MR. SOBOL: Objection.
A. No, I don't think that that would be a conclusion that I would agree with.
BY MR. ROTH:
Q. And why not?
A. The more effective your marketing is, the more you want to spend on it.
MR. SOBOL: An answer I understood.
BY MR. ROTH:
Q. We spoke briefly about your errata yesterday. Can you just tell me how did that errata come about?
A. That came about from review partly, my very careful review as I was preparing for this deposition, and the staff doing the same.
Q. Got it.
And then why did it come in the

Page 524

form of a memo from Mr. McCluer to you and Mr. Sobol?
A. I'm not sure I can answer that question.
Q. But it sounds like the errors were identified some by you and some by the staff?
A. Yes, that's correct.
Q. Do you know who caught the Table 3 error?
A. That was me.
Q. I feel bad for the staff on that one. And what about the --
A. I'm not the yelling type.
Q. And what about the statistical significance error, was that you or the staff?
A. That was the staff.
Q. Let's turn to your indirect model.
A. Okay.
Q. So you talk about your indirect model beginning at paragraph 78 of your report.
And I guess just taking a step

Page 525

back before we get into specifics: Do you have a preference for your direct over your indirect model in this case?
A. I believe they have strengths. Each of them has strengths, so in my opinions, I have not favored one over the other.
Q. In general when you perform regression analysis, do you have any preference for a direct approach versus an indirect approach?
A. No preference. I think these kinds of models are really context specific.
Q. And if you look at page 53, paragraph 78, you start by saying: As noted earlier, the direct method of estimation is limited in part by the extent to which we can measure and include in the models all of the tactics allegedly employed by defendants, including manipulation of various professional societies and accrediting bodies.
Did I read that correctly?
A. Yes, you did.
Q. And that's based on the

Page 526

allegations that you reviewed?
A. That's correct.
Q. Would you agree that if a defendant did not engage in promotion other than the detailing measured by the IPS data, the direct model would be a more appropriate measure of that particular defendant's impact on the aggregate MMEs?
A. My assignment was to calculate aggregate impact, so I have not considered how to calculate impact for a single defendant.
As we talked about yesterday, I think there are some complicated questions about how to deal with the spillover effect, so I have not undertaken to do that.
Q. As we've discussed fairly exhaustively, your direct Model B explains over 99% of the variation in MME sales based on the detailing data in IQVIA.
A. Yes, it does.
Q. Does that not suggest that the effect of all of these other types of promotion is negligible at best?
A. It may well be the case that

Page 527

the amount of variation that is picked up by a broader measure of promotion would not be so much more. The indirect model is conceptually quite different, however.
Q. So if you compare Table 5, which is on page 61 -- let's take a step back, lay some foundation.
A. Sure.
Q. So Table 5 on page 61 is the output of your indirect model, correct?
A. It is.
Q. Okay. We talked yesterday about Table 2, which is the output of your direct model and appears on page --
A. Should I bend the corner so we can go back and forth?
Q. Yes, good idea.
So I want to compare the direct output in Table 5 on page 61 -- sorry, strike that.
I want to compare the indirect model output in Table 5 on page 61 with the direct model output in Table 2 on page 51.
A. Okay.
MR. SOBOL: Do we have a graph

Page 528

of this somewhere?
THE WITNESS: Not in my report.
MR. ROTH: Just for you. I don't think we've seen that. I would love to see it.
BY MR. ROTH:
Q. So looking at the two tables next to each other, I guess just first taking the bottom line, in Table 2, the direct Model B estimates that 44.9% of MMEs are attributable to defendants' detailing.
Do you see that?
A. Yes.
Q. And in Table 5, the indirect method suggests that 67% of MME shipments are attributable to defendants' detailing; is that right?
A. That's correct.
Q. So that's a 22% delta -- well, that's a bad question because that's not how math works.
MR. SOBOL: Right.
BY MR. ROTH:
Q. It's 22% higher -- well, the numbers are what they are, but it's 44.9%

Page 529

and 67% -- it's actually 50% higher, I think, if I'm doing the math right.
A. It is 22 percentage points or about 50% higher than the direct estimate.
Q. You said it better than I could.
How is that possible given that you had a 99% R-squared in the direct model that your indirect model could estimate twice as much impact by defendants' promotion?
A. As I mentioned, they are conceptually very different kinds of analyses, so whether or not detailing explains the vast majority of the variation in sales, it does not account for -- it accounts for a smaller percentage of total sales, so the magnitude of effect is not the same thing as the amount of variation explained, right?
And the indirect model takes the position that there are these long run factors that may -- that we can see are relevant to demand in -- across areas, and if we extend those forward, looking at the growth in MMEs only as a result of those

Page 530

factors, that's another version of what the world would have been like.

It assumes, again, that the drivers of the massive growth we saw were only related to defendant promotion, and so it allows defendant promotion to affect sales in a broader way than the direct model does.

Q. In the direct model, I believe you went through 2018; is that right?

A. Yes. There were differences in data availability, so yes.

Q. Right. So that was what I was going to ask you.

Direct goes through 2018, indirect only goes through 2016?

A. Yes. And as I'm sure we'll get to also, because the ARCOS data start in 1997, I do, I backcast for '95 and '96, but really I'm starting in 1997.

Q. Got it. So direct, you go '95 to 2018; indirect, you go from '97 to 2016.

A. That's correct.

Q. Okay. And that's just because of just data limitations?

A. That's correct.

Page 531

Q. If you had the other years, you would use them in the indirect model?

A. That's correct.

Q. If you look at paragraph 82 of your report, you describe your indirect model as a form of residual analysis.

Do you see that?

A. Yes.

Q. And can you explain what a residual analysis is?

A. Well, a residual is the leftover part, and so a residual analysis is an analysis that draws inferences not from something included, but something excluded.

Q. Sort of like in accounting, when you depreciate something, what's left after you've depreciated it is the residual?

A. Is it? Yeah, perhaps.

Q. Except if the depreciation somehow appreciates, but we won't go there again.

What is the baseline of your indirect model?

A. The baseline for the indirect model as I just mentioned is the 1997 level of MMEs.

Page 532

Q. And you chose that because that was the earliest year available in ARCOS?

A. Yes, that's correct.

Q. How did you construct the explanatory variables you used in the indirect model?

A. The explanatory variables come from a variety of sources that I think we reviewed at a very high level yesterday. They're county level -- we haven't exactly talked about. So this is a county level cross-sectional analysis and we bring in data from a variety of government economic sources and other sources to capture county-level information.

Q. And we spoke about this a little yesterday with respect to Professor Cutler.

A. Yes.

Q. But the same question for you: Why did you decide to use national data and do a national model for direct regression, but then do your indirect regression analysis based on county-level data?

Page 533

MR. SOBOL: Objection, asked and answered.

A. Sure. The time series analysis that I did is appropriately done at the national level. We're trying to calculate national aggregate impact and the factors that drive sales over time make sense to do in -- at a national level there. We don't have promotional data at a county level, so it would not be possible to do a direct model at this level.

On the other hand, and this is why the indirect model complements the direct model, we can look cross-sectionally at variation in these socioeconomic and demographic variables because there's a fair amount of cross-sectional variation, and get reasonably precise estimates of the effect of those factors on MMEs.

And so the cross-sectional model works at the county level, and then rather than having to estimate the effects of those variables over time, we can trend them forward based on the cross-sectional analysis.

Page 534

BY MR. ROTH:
Q. If you look at paragraph 79, which is on page 53, you say: The indirect model begins with a regression analysis of the relationship between opioid sales and the demographic, economic and healthcare characteristics of an area ideally during the period prior to the misconduct.
Do you see that?
A. Yes, I do.
Q. So what do you mean when you say ideally it would be from the period prior to the misconduct?
A. Well, to the extent the misconduct is affecting the relationships between the right-hand side variables, those are the demographic, socioeconomic and healthcare variables that we include, estimation during this period could -- could affect the results.
And again, the level of MMEs in 1997, if the allegations are true, are already affected by the misconduct, but I believe this makes my analysis conservative by starting two years into the damage

Page 535

period -- or not the damage period, but the period of alleged misconduct.
Q. So you're taking data from the period of alleged misconduct in 1997 because your assumption is the period of alleged misconduct will be proven back to 1995?
A. That's correct.
Q. And you say this makes it conservative because the factors may have already been influenced and thus there would be a higher likelihood to see prescriptions from the demographic factors which have some effect of the misconduct already?
A. Potentially.
Q. Okay. And what would be your basis to think that the demographic, economic and healthcare characteristics in Summit or Cuyahoga Counties were already seeing the effects of opioids in 1997?
A. Wait, so just to be clear, actually, the -- what you just said doesn't quite make sense, so let me just -- I probably should have provided a much longer answer to the last question.
So what the two things that

Page 536

starting the analysis in 1997 do. One is I start already with a level of MMEs that if the allegations are true, they're inflated.
And, two, what I was trying to say is it's not that the socioeconomic status of the counties is affected, although that can certainly happen in the long run, but instead that the relationship between socioeconomic status and MMEs may have already been affected by the promotion.
So, you know, if, for example, the marketing is differentially affecting certain groups, then that could show up in the cross-sectional analysis, and so that's what I meant.
Q. And the reason you say it's conservative is because directionally you would think that the marketing would cause those factors to predict more MMEs than they would absent the marketing having already occurred?
A. Yes. And again, the first part, the fact that the levels directionally, again, under the assumption that the alleged misconduct had been occurring for two years,

Page 537

the levels would certainly be inflated relative to a but-for scenario in which there was no misconduct.
Q. Do you agree that for an indirect regression you should include any variable that might impact opioid sales?
A. For the indirect regression, I am including all the variables that should be cross-sectionally associated with that, so they -- just to be clear, that these are variables that can be measured at a county level, so not individual patient level, but at a county level will vary across counties and will predict use.
Q. And if there are variables that are cross-sectionally related to sales that are omitted, that could cause issues with overestimating the amount of sales impacted by promotion?
A. In any regression model, an applied economist will have to consider the possibility of omitted variables. It is also in tension with the idea that if you throw in hundreds of variables, you get nonsense soup out of it, and so there's always going to be

Page 538

some tension there, but certainly one considers important omitted variables.
Q. Yeah, I mean, if I understand it, the point of an indirect regression is to essentially solve for a variable by including everything but that variable that explains or could explain the outcome?
A. Yes. I just want to be clear that the word "everything" makes it seem like you could actually estimate a regression with hundreds of variables. There are degrees of freedom. There can be problems from trying to put everything in.
So in principle, you're right. We're trying to make sure that we include the important factors, and I believe I have done so here.
Q. Okay. So I want to talk a little bit about the mechanics first.
So you look at opioid shipments by county, correct?
A. That's correct.
Q. And why did you use shipments in your indirect model as opposed to prescriptions?

Page 539

A. These are words that describe the same thing in effect. So these are the ARCOS data. They use the terminology shipments. They don't track prescriptions. They track controlled substances that move from one set of hands to another. And so these are using their nomenclature.
At the end of the day, I -- these are MMEs, just like my MMEs in the direct model. They correspond. And, in fact, if you graph the two sets of data, they're very close.
Q. Can the IQVIA NPA data be disaggregated to a county level?
A. It cannot. Actually, I'm not a hundred percent sure as I sit here. Again, as we talked about yesterday, it's the detailing data that definitely can't be disaggregated. I can't remember whether the NPA can be disaggregated too.
Q. So as you sit here, you're not --
MR. SOBOL: You mean on its own as opposed to using other tools?
MR. ROTH: No, I just mean

Page 540

generally.
BY MR. ROTH:
Q. My question, just asking it more broadly, is -- and it sounds like you don't know the answer, so let me strike that and start with a clean question.
You don't know whether you could have used the same IQVIA data for MMEs used in your direct model in your indirect model at a county level?
A. I don't. I think the NPA is just a national-level dataset. I did compare MMEs in total in the ARCOS data to the IQVIA data, and I found them to be almost identical.
I note one place where the ARCOS data are not detailed enough to allow me to omit certain Schedule III codeines and hydrocodones, I think. Yeah.
Q. And that was going to be my next question.
A. Sure.
Q. So if you had used IQVIA data, you could have taken out the Schedule IIIs, but because you used ARCOS data, you had to

Page 541

leave certain Schedule IIIs in your analysis?
A. That's correct. They're not -- you can't identify them because the data aren't granular enough.
And I note in my report that that affects about 2?%. Just to be clear, I realized it's not an error, but it's not a hundred percent clear that that 2?% is really of those classes, of those molecules that have both Schedule II and Schedule III drugs, it's less than 1% of the total.
So again, when I compared the ARCOS MMEs and the IQVIA MMEs, they look almost identical.
(Interruption by the reporter.)
MR. ROTH: I think we need a quick break.
THE VIDEOGRAPHER: The time is 9:04 a.m. We're off the record.
(Recess taken, 9:04 a.m. to 9:16 a.m.)
THE VIDEOGRAPHER: The time is 9:16 a.m. We're back on the record.
BY MR. ROTH:
Q. Just to go back to something we

Page 542

were talking about before the break, so your testimony is that picking '97 is conservative because the unlawful conduct based on your assumptions started in '95, correct?
A. Yes.
Q. You are aware that many of the drugs at issue in this case were not on the market in 1997?
A. I'm aware that certainly some of the drugs enter later, yes.
Q. So for manufacturers who did not have any drug on the market in '97 or even '98 or '99 or until later, you actually did choose a pre-misconduct period for those manufacturers?
A. Well, again, I have been asked to characterize the aggregate impact of marketing on sales here, so I haven't -- and I'm certainly not a lawyer, but I haven't given a thought to allocating liability across defendants in any way. I would acknowledge that some defendants entered later than that with some drugs.
Q. Right. And because you looked at an aggregate, if a single manufacturer had

Page 543

a product on the market, the remaining manufacturers would all be subject to whatever the aggregate model shows as the impact from that one product even though it wasn't theirs?
MR. SOBOL: Objection.
A. Well, I think that you misunderstood the cross-sectional analysis. So again, the cross-sectional analysis is really capturing the effect of things like the age distribution and employment and the like. So that's not a question of something to which liability is being attached.
So it's really just trying to get a precise measure of those effects, and yes, that's the basis for projecting forward, but the projections forward, they don't assign any liability to those early relationships.
BY MR. ROTH:
Q. And just so we're perfectly clear, none of the models or the work you've done to date allows you to allocate liability to an individual defendant in this case, correct?

Page 544

MR. SOBOL: Objection.
A. I don't know the answer to that question because I don't know how liability would be allocated. The models calculate aggregate impact, and as I've shown in Table 3, we can change that aggregate.
It is possible -- again, I haven't been asked to do this, but it is possible to use a similar approach to construct one kind of liability allocation, which would be to look at the levels of detailing across defendants and use that in Table 3 in a different way.
BY MR. ROTH:
Q. None of the work or models you've done in this case allow you to allocate liability to a specific defendant based on only that defendant's alleged promotion?
MR. SOBOL: Objection, asked and answered.
A. Well, again, I'm not a lawyer, but it seems to me that one method of allocating liability is in proportion to one's detailing efforts, and I have an

Page 545

aggregate impact that can be allocated in proportion to detailing using a similar approach to the way Table 3 assesses aggregate impact for different combinations of defendants.
BY MR. ROTH:
Q. So I understand that your Table 3 allows you to allocate to defendants their share of the promotional contacts in the data, correct?
MR. SOBOL: Objection, asked and answered.
A. It is not based just on their share of the promotional contacts, but it's based on the difference in aggregate prescribing that would occur with and without their marketing happening.
So it's not -- as we talked about yesterday, it's not strictly -- it goes through the model.
BY MR. ROTH:
Q. Okay. Your assignment was to develop an aggregate model of the impact of detailing on MMEs, correct?
MR. SOBOL: Objection.

Page 546

A. Just to be crystal clear, my assignment was to estimate aggregate impact using the best available methods.
BY MR. ROTH:
Q. Right. And you've said numerous times throughout the last two days that your assignment was not to determine liability, correct?
A. Yes. I am -- I am not going to -- my opinions relate to the effect of marketing, and how that relates to liability and recovery is not part of my assignment.
Q. Okay. So unless the court allows the plaintiffs to prove liability based on each individual defendant's share of aggregate marketing, you have no mechanism to allocate liability on an individual defendant basis?
MR. SOBOL: Objection, asked and answered.
A. I think you're asking me for a legal opinion. I don't know. It seems that the court could -- could allow plaintiffs to allocate liability in a number of different ways. I don't know how that would work.

Page 547

BY MR. ROTH:
Q. I understand that. I'm not asking you for a legal opinion. I just want to understand what you're going to do at trial, okay? Okay?
MR. SOBOL: The buzzword is -- when you're using the word "liability" in the question, that's the buzzword that's sending her down that road. So if you -- I'm coaching you now.
MR. ROTH: Well, I understand that, but I'm also trying to -- I know you guys want ultimate flexibility on your side but you shouldn't have it on this point, so I want to make sure the record is clear, okay?
BY MR. ROTH:
Q. Professor Rosenthal, your regression models that you have done to date do not allow you to allocate causation to individual defendants in any way other than as a ratio of those defendants' detailing contacts against the market aggregate detailing contacts?
MR. SOBOL: Objection to form, asked and answered.
But you may answer.
A. You have used the terminology as a ratio, and that is not what happens in Table 3.
So again, I don't know what the court will want, but what I can do with my aggregate model is I can use the econometric results and create different but-for scenarios, one set of which would be to focus on individual defendants isolated from others.
That's similar to what I've done in Table 3, but that's not allocating based on a ratio. It's rerunning the but-for scenario, the predictions using a defendant's detailing, and that detailing is not just a single number. It's a time series.
BY MR. ROTH:
Q. Let me try this again.
Your regression models that you have done do not allow you to allocate causation to individual defendants in any way other than separating out those defendants' detailing contacts from the market aggregate detailing contacts?
MR. SOBOL: Objection to form, asked and answered.
A. My analysis allows me to predict but-for prescriptions based on any level of detailing, including the assumption that only a single defendant's detailing was unlawful, and there may be other ways of using the aggregate model to estimate liability, except that I'm not a liability expert. There may be other ways that I just don't know of.
I can identify MMEs. I can identify detailing for each defendant. That information may be used in other ways that I haven't thought of because I don't know what the court will need.
BY MR. ROTH:
Q. How do your models allow you to predict but-for detailing assuming only a single defendant's detailing was unlawful without running afoul of the endogeneity issues that we've discussed?
MR. SOBOL: Objection.
You can answer.

Page 550

A. Because again, the endogeneity issues are in the estimation of the parameters. The but-for scenarios take the estimates that are created at the aggregate level, and they feed into it an alternative set of detailing information. So they're post-estimation.

Endogeneity is pre-estimation, and all I'm doing is changing the simulation of the but-for scenario.

BY MR. ROTH:

Q. Let's go back to the indirect model for a bit.

Based on your assertion that opioid pharmaceutical efforts are national in scope and that marketing messages are developed as a whole, would you expect a single detail in one county to have the same effect as a single detail in another county?

MR. SOBOL: Objection.

You can answer.

A. I don't know what the variability and the effect of detailing is per se. I expect that there would be some variation in the effectiveness of detailing

Page 551

from situation to situation.

And my model and my assumptions in the indirect model, since I don't model promotion directly, is that what I'm aiming to calculate is the average effect, and therefore, calculate the aggregate impact from that average.

BY MR. ROTH:

Q. Is it possible that shipments to a county could understate or overstate consumption of opioids in that county?

A. Yes, it is possible that shipments to a county -- so once we get to the county level, there are -- there are issues related to diversion.

Q. And I think Professor Gruber describes that as a transshipment problem in his report?

A. I think he does. There's a fancy name for the Florida transshipments, I can't remember what it was called, but yes.

Q. Did you consider using geographic designations that account for commuting patterns?

A. No, I did not. The

Page 552

county-level data I think are the most appropriate level of analysis. Any geographic unit will have some people moving in and out, but the county level, I think is an appropriate level of analysis.

The economic and sociodemographic -- demographic and socioeconomic variables are measured at the county level, and we think about these sort of economic issues as being approximately captured at the county level.

Q. Did you consider core-based statistical areas instead of counties?

A. I did not.

Q. For the same reason that you just gave?

A. Yes. There are -- the ARCOS data are at the county level, and again, most economic data are tracked at the county level. There are some data that are focused on urban cores, but not the kind of comprehensive data that I used here.

Q. Did you consider using metropolitan statistical areas?

A. The same answer. I did not.

Page 553

That would be aggregating up. MSAs also split certain counties. It doesn't make sense to me to move up a level. The county level is more granular than the MSA level.

Q. In certain places, though, the county level may actually be larger than the MSA, right?

A. That is true in urban areas. In rural areas, MSAs include multiple counties. They're not precisely overlapping, I know from having done some matching at some point, they're not easy to cross-walk.

Q. Okay. So back to paragraph 83 of your report. So you say as you just said that you used county-level ARCOS data on shipments of prescription opioids between 1997 and 2016, correct?

A. Yes.

Q. But ARCOS actually doesn't have county-level data, does it?

A. The -- I believe the data are mapped to counties.

(Whereupon, Deposition Exhibit Rosenthal-22, Data Appendix, was marked for identification.)

Page 554

BY MR. ROTH:
Q. That's right. So let's look at Exhibit 22, which is the data appendix that I believe you shared with Professors Cutler and Gruber?
A. That's right. As I mentioned, the ARCOS data for me come through Compass Lexecon.
Q. Okay. So we spoke yesterday about who helped you with your report, and it was Greylock McKinnon. Other than giving you the ARCOS data, did Compass Lexecon have any role in the preparation of your expert report?
A. No role in the preparation of my expert report, no.
Q. And did you speak with anyone from Compass Lexecon directly?
A. Yes, we talked about those meetings, and perhaps some of the calls, there were people from Compass Lexecon on those.
Q. But in terms of your regression analyses and running the Wald statistical tests, that was all Greylock and yourself;

Page 555

that was not Compass Lexecon?
A. Yes, that's correct, my staff ran these.
Q. Okay. So if we look at Exhibit 22, turn to page 11, and it's a section on the ARCOS prescription shipment data.
Do you see that?
A. Yes.
Q. Do you know who prepared this document?
A. I do not, no.
Q. It was not you or your staff as far as you know?
A. It was not me or my -- it certainly was not me. I do not believe it was my staff.
Q. So on the top of page 12, it says: The Drug Enforcement Agency, DEA, provides data on shipments of prescription opioids over time and across geographies. This appendix describes the source of these data and the steps taken to process and set up the data for analysis.
Do you see that?

Page 556

A. Yes.
Q. Then also on page 12, we'll get to this later, but it shows the DEA drug codes and names in the ARCOS data which are at the molecule level.
A. That's right.
Q. And that was why you couldn't separate out the Schedule IIIs, as we discussed?
A. That's correct.
Q. And then if you turn to page 13, the next page.
A. Yeah.
Q. Sorry, it's actually on page 14. That's my errata.
Do you see the section mapping shipments from three-digit ZIP codes to counties?
A. Yes, I do.
Q. It says: As noted above, the most detailed geographic area reported in the public ARCOS reports is the three-digit ZIP code. Three-digit ZIP codes are based on the first three digits of standard U.S. postal ZIP codes. These areas typically, but not

Page 557

exclusively, span across more than one county and thus are not directly comparable to the county level of data available for mortality, crime and geographic -- I'm sorry, crime and demographic and economic statistics.
Do you see that?
A. I do.
Q. And were you aware of that issue?
A. I was at one level. I had forgotten that there was a cross-walk from three-digit ZIPs, which themselves, again, are geographic areas that vary in terms of how big they are.
Q. Do you know how Cuyahoga County compares to the three-digit ZIPs that are reflected in the ARCOS data for that area?
A. I'm sorry, I do not.
Q. Do you know how Summit County compares to the three-digit ZIPs for that part of Ohio?
A. No, I did not.
Q. And if you look at page 15, it says: In order to link the ARCOS shipments data to the other county data, we have

Page 558

allocated shipments based on the weighted average population of census block centroids, center points that fall within each county that a three-digit ZIP code crosses. And then this means that when a three-digit ZIP code crosses county boundaries, we use the population at the census block level to estimate the share of population across counties for the three-digit ZIP.

Do you see that?

A. I do.

Q. An underlying assumption to this approach is that the shipments per capita within a three-digit ZIP code are the same across census blocks.

Do you see that?

A. Yes.

Q. And when it says "we have allocated," do you know who did that work?

A. Compass Lexecon, but I don't know who in particular.

Q. And did you do anything to test Compass Lexecon or whomever's underlying assumption that shipments per capita within a three-digit ZIP code are the same across

Page 559

census blocks?

A. I did not, no. I don't think it's possible to do that with these data because there aren't census block level data in ARCOS.

Q. And then they explain their methodology below with the mathematical formula of how they allocated ARCOS drug shipment totals to the counties based on population share?

A. That's right.

Q. And that's not an analysis you've seen before?

A. I'm sorry, what do you mean? I've seen this data appendix.

Q. Have you seen the analysis for how Compass Lexecon allocated ARCOS shipments to the counties?

A. I guess I don't know what you mean by "seen." I understand that they allocated based on population using this formula, so have I seen the individual calculations, is that what you're asking?

Q. Correct.

A. No, I have not.

Page 560

Q. Okay. And you would agree that just because a product is shipped to certain counties does not mean it's consumed there?

MR. SOBOL: Objection, asked and answered.

A. I think as explained in -- in the Cutler report, and Gruber may have said it also, to the extent that shipments are moving from one county to another, this regression methodology will -- it will just contribute to noise essentially in the regression.

So it's -- that -- the fact that there may be understatement of shipments in Ohio -- I think that's the premise here -- because there's overstatement somewhere else because they moved from one place to another, that itself won't bias this analysis. It may create some noise.

BY MR. ROTH:

Q. What is your basis for thinking there's an understatement of shipments to Ohio in the ARCOS data?

A. Well, again, it's really reading Cutler and Gruber's reports and the

Page 561

notion of the -- I guess it was the Oxy Express, so the shipments go to Florida, but they ultimately end up in Ohio and Kentucky and places like that.

Q. And have you done any analysis as to how the Oxy Express influenced consumption of prescription opioids in Ohio?

A. No, I have not.

Q. Do you agree that the census data on population is not necessarily connected to where opioids are consumed?

A. Allocating shipments based on population is a reasonable approach, and I think, you know, as they say in footnote 24, this is -- it's very common that we make such geographic cross-walks just because the way data are presented. It's a reasonable basis for allocating shipments in my opinion.

Q. I understand you think it's a reasonable basis. I'm not asking that.

I'm just asking the factual question. Where the population is shown in the census data is not necessarily correlated to where the shipments are consumed?

MR. SOBOL: Objection.

A. Well, it almost --
MR. SOBOL: Asked and answered.
A. It almost certainly is correlated because you need peoples -- people to have consumption, but exactly what the relationship is, I can't say for sure. But again, it almost surely is a major factor in determining where the consumption is. It may not be perfectly correlated.
BY MR. ROTH:
Q. And people don't necessarily consume prescription opioids in their homes, right?
MR. SOBOL: Objection.
A. Well, I don't think that that's the -- that's the relevant question for my analysis. Again, I'm really looking at what factors predict shipments here, so wherever people consume them.
BY MR. ROTH:
Q. But you understand that your analysis is feeding into Professor Cutler's analysis and Professor McGuire's analysis who are trying to compute harms and damages occurring within Summit and Cuyahoga County?

A. It's true, but the way my indirect analysis feeds into Professor Cutler's analysis is in the aggregate.
Q. If you turn to paragraph 84, that lists, I believe, all the variables you include in the indirect model; is that correct?
A. Yes.
Q. So you've got three categories, demographic, economic and healthcare variables.
A. That's right.
Q. Let's take those one at a time.
So the demographic variables you include are essentially gender, male versus female?
A. Yes.
Q. The percent in different age groups set out in your report as to how you divided them, it looks like into five different age -- six different age group -- five different age groups?
A. Sure. Sorry, these are just standard census categories.
Q. Okay. Another demographic

factor you included is the percent of the population that is white, black and Hispanic --
A. Yes.
Q. -- so race.
And then the share of the population in four different education groups, correct?
A. Yes.
Q. And the percent of the county identified as urban, correct?
A. That's right.
Q. And are all of those census categories?
A. I believe so, yes. I think they all come from the ASEC that we talked about.
Q. Okay. And then in the second category, economic variables, you included the unemployment rate?
A. Yes.
Q. You included employment-to-population ratio?
A. Yes.
Q. You included the distribution

of employment by major industry sector?
A. Yes.
Q. You included median household income?
A. Yes.
Q. You included the poverty rate?
A. Yes.
Q. And you included the county's population?
A. Yes.
Q. And then for healthcare, you only included two variables, correct?
MR. SOBOL: Objection.
You can answer.
A. Yes, I included two healthcare variables.
BY MR. ROTH:
Q. And one was the percentage of the population without insurance, correct?
A. That's correct.
Q. And the second variable is the number of cancer deaths, correct?
A. That's correct.
Q. Why did you include a variable to account for the percentage of the

Page 566

population without insurance?
A. I included that variable because I thought that there might be relatively widespread coverage differences across counties and that that might explain, as I think we talked a little bit about yesterday, the extent to which people go to the doctor and therefore get a prescription, and also, their likelihood of filling a prescription.
Q. Insurance coverage, though, is not a variable you included in your direct model?
A. That's correct. And I'm sure we'll continue to come back to this, but the cross-sectional variation, insurance coverage is a lot more substantial across counties than it is over time.
Q. In your -- what I'll call thought experiment, which we'll talk about in a minute, you include as potentially medically allowable prescriptions, surgery and trauma; is that right?
A. Yes. I guess we'll discuss the right words to describe that, but yes, so as

Page 567

the potentially appropriate uses, something like that I think is what I say, that surgical and trauma conditions, yes.
Q. But in your indirect model you don't have any variables for either surgery or trauma?
A. I do not, no.
Q. And why is that?
A. Well, the data from the healthcare utilization project that we will -- we'll talk about later, those cannot be disaggregated. There are some state-level data, but they're considered to not be reliable for that purpose, so those are national data only.
And ultimately, the trends in those -- sorry, wrong question, I was answering the direct model.
And ultimately, those factors, the numbers there, I don't believe that we have reliable estimates across counties over the entire time period.
Q. I'm a little confused because you just said the surgery and trauma figures --

Page 568

A. Yeah.
Q. -- cannot be disaggregated, but I thought in your last section you have a disaggregation of potentially appropriate MMEs for Summit and Cuyahoga that includes trauma and surgery.
A. Yeah, the HCUP data, those data are not at the county level. The other data are at the county level, the Area Health Resources File. So I was distinguishing between those two.
And in general, you can see, when we get to the appropriate uses, that the -- those trend downwards, and so even if we were to include those in the model and they had a cross-sectional relationship, it would not cause the indirect estimate to be increasing.
Q. But you didn't actually include those in the model?
A. I didn't, no.
Q. Did you consider any other variables to include in any of the three categories, demographic, economic or healthcare, in your indirect model, aside

Page 569

from the ones we've discussed?
A. No, these are the variables -- these variables are based on previous literature, all of those demographic and socioeconomic variables come from an assessment of what has been shown to be associated with opioid use.
Q. And what literature assessing the variables associated with opioid use are you relying on?
A. Well, I don't think I have a citation in here, so I don't know a specific paper as I sit here. Again, these are -- these are variables that economists studying opioid use have used from the census data.
This is the source of data that have been used by researchers. I think most of that literature is cited in Professor Cutler's report.
Q. Okay. And is -- was the list of variables you would use in your indirect model a subject of discussion between yourself and Professor Cutler?
A. I can answer that if counsel were present?

Page 570

MR. SOBOL: Well, yes or no.
A. Yes.
BY MR. ROTH:
Q. So if you look --
MR. SOBOL: You got so used to just running on that you forgot you could answer yes or no.
BY MR. ROTH:
Q. If you look at page 25 of Exhibit 22.
A. Okay. This is the data appendix?
Q. Yes.
A. Yeah. The Table 2?
Q. Yes.
So this is a table that reflects economic and demographic variables with data sources and years reported.
A. Uh-huh.
Q. And this is the shared appendix, but I assume these are the variables we've been discussing that you used in your indirect regression?
A. Yes, they are.
Q. Okay. So if you look at

Page 571

several of the rows, there's a shaded gray bar that says Interpolated.
Do you see that?
A. Yes, that's right.
Q. And what does that mean?
A. Well, some of the variables come only from the decennial census, so we have them for every ten years, so a linear interpolation was used between those ten-year points.
Q. And how do you know it was a linear interpolation?
A. Well, I should read more closely. I believe it is a linear interpretation, but my memory is not to be trusted.
Q. You know what, you're right. Actually, it says that at the bottom of the chart. Interpolated values are a linear interpolation between the preceding and following measured value.
A. Someone should do something about that font size.
Q. Who performed the linear interpolation on the census data for the

Page 572

variables that were interpolated?
A. I do not know the specific individual. These were constructed by Compass Lexecon.
Q. Did you consider picking a year where you did not need to do interpolation, such as the year 2000, as your baseline?
A. No, I did not consider that.
Q. Are you using interpolated values for these variables in your 1997 baseline?
A. Yes, I am.
Q. Is it possible the interpolated variables affect the baseline estimated relationship between the explanatory variables and shipments per capita per day?
MR. SOBOL: Objection to form.
A. These socioeconomic and demographic variables change very slowly, and I believe the linear interpolation method is entirely appropriate.
I do not believe that they are likely to cause any impact on my analysis, but if any, they would be a source of mismeasurement, which would dampen -- which

Page 573

would basically cause noise, but not bias.
BY MR. ROTH:
Q. Have you studied the linear interpolation that was done and how it might impact your analysis?
A. Well, I'm not exactly sure how one would study such a thing. Again, we undertake the interpolation because those data were not captured in those years, so there's not a gold standard to compare the linear interpolation to.
Q. But what you could do is pick a year where no interpolation were needed and compare the results from that year, say 2000, against '97 with the interpolation?
MR. SOBOL: Objection.
A. Well, as we discussed earlier, my effort was to undertake the cross-sectional analysis in a year that was unaffected by the alleged misconduct, and 1997, while imperfect, is a bit closer to that.
2000 would be a time period in which the alleged misconduct was well under way, so I did not consider such an analysis.

Page 574

BY MR. ROTH:
Q. And when you say the alleged misconduct was well under way in 2000, that's based on your assumption that it started in 1995 as opposed to a review of actual promotion that occurred between '95 and 2000?
MR. SOBOL: Objection.
A. Well, again, I am assuming that plaintiffs' counsel will prove their case. As you know, there's quite a bit of evidence that I can't evaluate from a legal perspective that I can see as a layperson that suggests marketing messages related to opioids were, in fact, dampening the sense of the addictive properties of these drugs.
Whether or not that's unlawful I can't say, but I can certainly see that what the allegations describe was happening during this period.
BY MR. ROTH:
Q. Do you understand -- well, strike that. Let me ask it a different way.
Does your model assume that unlawful detailing occurred even if that detailing were solely based on FDA-approved

Page 575

labels or marketing materials?
MR. SOBOL: Objection, asked and answered.
A. Well, you're asking me to assume a hypothetical in that case, I think, that all marketing was based on FDA-approved labels.
BY MR. ROTH:
Q. I don't think so. I think what I'm asking is your model treats all of defendants' promotion as unlawful based on the assumption that you made based on the instruction of counsel, correct?
MR. SOBOL: Objection, asked and answered.
A. Yes. I have been asked to assume that plaintiffs will prove that in sum, defendants' marketing was unlawful.
BY MR. ROTH:
Q. Okay. And if, in fact, a defendant or subset of defendants only promoted using FDA-approved labeling and/or FDA-approved marketing materials, how does your model address that?
MR. SOBOL: Objection, asked

Page 576

and answered.
A. I think you're asking me a legal question, so I do not know whether such a hypothetical would have -- would exclude the possibility that the conduct was unlawful in some other way. I don't know.
BY MR. ROTH:
Q. Just assume my hypothetical is so, okay? Don't fight the hypothetical.
If for a given defendant it is proven that all promotion was solely based on FDA-approved labeling and FDA-approved marketing materials, your model still includes those promotional contacts in calculating the aggregate impact, correct?
MR. SOBOL: Objection, asked and answered.
A. I guess I'm trying to understand. We've been talking about my indirect model, which does not include a measure --
BY MR. ROTH:
Q. Yeah. I'm back to the direct for this question. I'm back to direct for this question.

Page 577

A. Going back to --
Q. Let me reask it because we're talking over each other.
If for a given defendant it is proven that all promotion was solely based on FDA-approved labeling and FDA-approved marketing materials, your direct model still includes that defendant's promotional contacts in calculating the aggregate impact, correct?
MR. SOBOL: Objection, asked and answered, misstates prior testimony.
A. I do not know whether a hypothetical in which the marketing were based solely on FDA-approved materials is in any way in contradiction to the assumption that that marketing can be proven unlawful. That is a legal question, the answer to which I do not know.
BY MR. ROTH:
Q. Now if you turn to paragraph 81 of your report, and now we're back to the indirect model.
In paragraph 81, you say:

Page 578

Based on these estimates of the relationship between the economic, demographic and healthcare characteristics of counties and opioid sales before the opioid epidemic took hold, the model can be used to predict opioid sales using only changes in the X-i variables over time.

Do you see that?

A. I do.

Q. And then you say: A modified version of this approach incorporates an estimated secular trend also using data from the pre-misconduct period.

Do you see that?

A. I do.

Q. So what is a secular trend?

A. Secular trend here, it's literally a linear trend that I calculate using sort of a long series of pre-alleged misconduct data.

Q. That's based on the growth rate in opioid sales from 1980 to 1995?

A. That's correct.

Q. And that trend would include obviously only the molecules that were

Page 579

approved and sold at that time, correct?

A. By definition, yes.

Q. And I think that would mean it would include morphine, pethidine, oxycodone, fentanyl and hydromorphone.

Does that sound right?

MR. SOBOL: Objection.

A. I am not a hundred percent sure so I would have to actually look at the INCB data.

BY MR. ROTH:

Q. So do you know which molecules are included in the secular trend and which are not?

A. The data from the INCB are like the ARCOS data, they're at the molecule level. I just -- as I sit here, I can't remember, but the analysis was done to include the analogous products, recognizing that there are new entrants that happen after 1995.

Q. Do you know whether or not the INCB data from 1980 to 1995 includes hydrocodone?

A. I do not as I sit here.

Page 580

Q. Do you know whether the INCB data from 1980 to 1995 includes propoxyphene?

A. I -- as I sit here, I do not. I'm trying to remember if it's actually in my Appendix D.

Q. If it is, I'm happy to look at it. I don't --

A. Yeah.

Q. -- know if it is or not. It may also be in that data appendix I gave you.

But so we don't get bogged down on it --

A. Sure.

Q. -- it's fair to say, whatever drugs are listed in the INCB data from 1980 to 1995 are included in the secular trend, correct?

A. I believe so, yes.

Q. And any drugs that are not listed in that data are not included in the secular trend?

A. I think that's right, yes.

Q. And if any of the opioids not included in the secular trend grew at a faster rate than those included, your

Page 581

indirect model would not fully account for the intended market-expanding effects of promotion for those molecules?

MR. SOBOL: Objection.

A. Again, adding the secular trend in my opinion is very conservative here to begin with. My intent was to capture all the relevant molecules, basically those that map to the market that I'm looking at post 1995, recognizing that there are changes over time.

And so this secular trend in my indirect model is intending to capture defendant -- non-defendant, sorry, promotion -- that's an important verbal errata.

So as already, because some of the defendants may be involved in that early data, they may be picking up some of the alleged misconduct, if some of it occurs before 1995, I think I'm not as concerned about underestimating that trend.

BY MR. ROTH:

Q. But just so I understand, if the opioids omitted from the secular trend grew at a faster rate than the included

Page 582

molecules, your indirect model would fail to account for the intended market-expanding effects of non-defendant promotion?

MR. SOBOL: Objection, asked and answered.

A. Again, I believe that I included the molecules that were appropriate for inclusion. I don't know that there are any that should have been included that weren't.

My intention was to capture the set of molecules that -- that were similar -- were basically the available alternatives over that period to -- as opioid analgesics. And if there -- I guess if there were any that are omitted, I could identify those and adjust the trend if need be.

BY MR. ROTH:

Q. Before your post-estimation secular trend and aggregate price adjustments, are your predicted values of shipments per capita per day influenced only by changes in the demographic, economic and healthcare explanatory variables?

A. I don't know what you mean by

Page 583

"only," but the -- as you can see in Table 4, there are a number of significant relationships across those demographic, socioeconomic and healthcare variables, and there are about 20 variables included there in total.

Q. And since you've directed me to Table 4, what does it mean, "no obs," is that number of observations, 404?

A. Yes, I'm sorry. We're not very generous with our shorthand, are we? Yes, that's the number of observations.

Q. What does that mean exactly?

A. That's the number of counties in the sample.

Q. Okay. And the R-squared of the indirect model is 33%?

A. That's correct.

Q. Which is not 99.6%.

A. As I note in the chapter, cross-sectional regressions never have the same R-squared as time series analysis.

Q. Did you consider the prediction intervals for your predicted shipments per capita per day?

Page 584

A. What do you mean by the prediction intervals?

Q. Yeah. Did you consider upper and lower bounds for your predictions?

A. You mean by setting the independent variables to extreme levels? I'm still not sure what you're talking about.

Q. Yeah, I think that's right.

A. I did not look at trying to predict out of sample. I'm interested in using these variables to be able to then take the trends in the underlying demographic, socioeconomic and healthcare factors and predict forward in the ranges that those variables hold. So I did not look at extreme values.

Q. Okay. If you look at paragraph 88, you talk about how you adjusted for price impact in the indirect model?

A. Yes.

Q. And then you say: There's little county-level variation in opioid prices so this variable does not appear in the cross-sectional model, despite the fact that my direct model shows a small but

Page 585

significant negative effect of price on sales over time.

Do you see that?

A. I do.

Q. And what is your basis for the statement that there's little county-level variation in opioid prices?

A. That's based on my knowledge and experience as a health economist who has done a lot of work on pharmaceutical pricing. As you may know, pharmaceutical manufacturers report list prices, and those list prices are the basis for retail transaction prices.

Q. AWP?

A. AWP.

Q. Have you done any analysis specific to opioid products and potential price variation across counties?

A. I have not calculated that variation in this matter, no.

Q. And in your direct model you acknowledge there is a small but significant downward effect of price on sales over time?

A. Yes, which is why I adjust for it here.

Page 586

Q. And how do you adjust for it? That's how you described it in paragraph 88, by changing the estimated coefficient on the drug price index?
A. So I used the estimated coefficient from the direct model and then the trend in prices in order to project that price effect.
Q. So you use your direct model's output for the price coefficient, and then as you say, adjust for the trend in prices?
A. That's correct.
Q. Okay. Can we agree generally that omitted variables can cause bias in regression analyses?
A. The concern about omitted variables is a ubiquitous one in any econometric analysis. I believe that I have appropriately captured the most important variables in my analysis.
Q. And do you agree that to the extent that other factors not modeled in the baseline regression contributed to increases in opioid shipments, the indirect approach has the potential to overstate the impact of

Page 587

promotion on shipments?
MR. SOBOL: Objection, asked and answered.
A. I'm not aware of any variables that should be in the model that would make a substantial effect here. If such a variable existed, it could affect the calculations in the way that you suggest.
BY MR. ROTH:
Q. Okay. You did not include a variable reflecting the number of military veterans in the counties, did you?
A. No, I did not.
Q. Do you agree the number of veterans in a county could increase the amount of MMEs sold?
A. I don't know as I sit here whether that's a reasonable thing to posit.
Q. You've not looked at any literature as to whether veterans require more opioids than other citizens?
A. I have not, and you have to keep in mind that there are a number of other variables in the model that will be correlated with the number of military

Page 588

veterans or any other sociodemographic group, if that's appropriate to call military veterans a sociodemographic group, such as the educational distribution, ages, those things may well pick up some effects, if any exist.
Q. Okay. But you didn't include veterans specifically?
A. I did not.
Q. You did not include a variable reflecting the number of doctors in the county, correct?
A. I did not include a variable reflecting the number of doctors in the county.
Q. Can we agree that the number of doctors in a county can affect the amount of MMEs prescribed and sold in that county?
A. It's possible, but again, the variables that are included in my model I believe would be correlated with the number of doctors in a county, so rurality, for example, will be correlated with the number of doctors, the percent uninsured will be correlated with the number of doctors, and I

Page 589

believe the included variables in my model are sufficient to pick up those effects.
Q. Okay. You did not include a variable reflecting the number of hospitals in a county?
A. I did not include a variable reflecting the number of hospitals in the county, and again, I believe the demographic and socioeconomic variables in my model will be correlated with the presence of hospitals, and therefore I am not concerned about the bias from that exclusion.
Q. Would you agree the number of hospitals in a county could influence the amount of MMEs prescribed and sold in that county?
A. I believe as a factor it could have some effect, and that the variables that I include in my model will be sufficiently correlated with that, that the omission of the number of hospitals will not bias my results.
Q. You did not include a variable reflecting the number of pharmacies in a county?

Page 590

A. I did not include a variable reflecting the number of pharmacies, and like any other measure of economic activity, I believe that will be strongly correlated with the socioeconomic variables that I do include in my model.
Q. Would you agree that the number of pharmacies in a county may increase the amount of MMEs shipped to that county?
A. Ignoring the fact that the other factors that I include may well account for that effect as an independent matter, the number of pharmacies may affect the number of shipments in a county.
Q. Did you include a variable on the incidence of cancer in a county?
A. I included cancer deaths rather than cancer incidence.
Q. And is it your view that cancer deaths is a sufficient proxy for the incidence of cancer?
A. Well, of course, cancer deaths will be substantially correlated with cancer incidence, and I included cancer deaths on the premise that opioids are indicated for

Page 591

end-of-life cancer treatment.
Q. Do you understand that opioids may be indicated for cancer pain even if it's not at end of life?
A. I understand that according to clinical experts there are certain cases where opioids may be indicated for cancer pain.
Q. Do you agree that cancer incidence may increase the amount of MMEs shipped to a county?
A. Actually, I was -- it is possible that cancer incidence does correlate with the number of MMEs per county, but very unlikely to me that adding cancer incidence to a model that has cancer deaths would contribute anything to explaining the variation in county-level shipments.
Q. You did not include a variable reflecting the number of individuals eligible for a pharmacy benefit through their insurer in a county?
A. I did not include a variable reflecting the number of individuals eligible for a pharmacy benefit in the county. Again,

Page 592

I believe that in particular, the percent uninsured will summarize the accessibility to coverage and that adding the pharmacy benefit piece will contribute very little given the more than 90%, I think more than 95% of people who have insurance also have a pharmacy benefit.
Q. But as we spoke about yesterday, the parameters of insurance coverage including a pharmacy benefit can influence the prescription and utilization of opioids?
MR. SOBOL: Objection.
A. While it may be true for an individual patient, you can see that my percent uninsured variable, is not statistically significant in this model, so again, accounting already for the population characteristics, the socioeconomic characteristics of the county, percent uninsured, which is clearly the first order measure, does not add any -- anything to this model in terms of explanatory value, and so getting even more granular than that I believe would not change the model.

Page 593

BY MR. ROTH:
Q. You did not include a variable reflecting the existence or number of pill mills in a county.
A. I did not include a variable reflecting the existence of pill mills. I think to control for that does not make a lot of sense to me, given that I believe it's -- that those may have been caused by the alleged misconduct.
Moreover, as with other variables not included of that supply side nature, I believe the socioeconomic variables are likely to explain a great deal of the variation in the existence of pill mills.
Q. So is it your position that the manufacturers' promotion created the diversion of prescription opioids through pill mills?
MR. SOBOL: Objection to the form.
A. I have not offered that opinion, but you asked me as to whether I would consider -- well, you asked me whether I included pill mills and my first reaction

Page 594

is that I would not consider that to be an appropriate variable to control for because it would essentially say, oh, yeah, this is -- this is expected. These pill mills are expected, and only changes in opioid prescribing outside of the pill mills would be subject to recovery.

As I understand the allegations, I would be very surprised if that would be an appropriate assumption.

Q. So in your view, you think the manufacturers should be responsible for the illegal prescription of opioids through pill mills?

MR. SOBOL: Objection.

A. I think you've gone a little too far, but in my view, I wouldn't just include such a variable like that without better understanding exactly what plaintiffs intend to prove.

BY MR. ROTH:

Q. Do you agree that the existence of pill mills can increase the amount of MMEs shipped and utilized in a county?

A. I believe that that is the

Page 595

concern with pill mills. Perhaps by their derogatory name, that is my presumption, that they do, in fact, make opioids more available than they otherwise would be.

Q. And more broadly, you did not include any variable reflecting the existence or volume of illegal prescribing in the county?

MR. SOBOL: Objection.

A. I do not have a variable on illegal prescribing in the county, no, I do not. And I would have the same concern about the extent to which that is to be considered an independent factor.

BY MR. ROTH:

Q. You don't have a variable for formulary placement of opioids in the indirect model?

A. Did we not cover that?

Q. We covered pharmacy benefits.

A. Oh, I'm sorry. I have not included a formulary measure and I'm not sure -- entirely sure what you mean by that. But I would say again, given that the percent uninsured, which is the first order measure

Page 596

of coverage and accessibility is not statistically significant in my model, I would not anticipate a more nuanced measure of the nature of coverage to affect my results.

Q. You did not include a variable to account for the introduction of Medicare Part D in your model?

A. Well, the indirect model is a cross-sectional model of 1997, which is a number of years in advance of Medicare Part D. And again, given that the percent uninsured seems to have no relationship in the cross-section to opioid use, then Medicare Part D would not play a role in the model.

Q. You did not include a variable for promotion by non-defendants in the model, correct?

A. My time trend, as I describe it, was intended to proxy for that, but --

Q. Right. So you have a separate secular trend.

A. Yes.

Q. You don't have it as a separate

Page 597

variable.

A. That's right, it's not a separate variable, and that's why I include the time trend.

Q. Are you aware that non-defendant promotion accounts for approximately 32% of the promotional contacts in the IPS data, on a national level?

A. I'm hoping somewhere that's in my report. I'm willing to believe you. We certainly calculated that figure.

Q. Okay.

A. I just don't want to go back to the dreaded Table C.

Q. Yeah, we may later, but we'll stop for now on there.

A. Okay.

Q. All of the variables we just discussed that you excluded from your indirect model are likewise excluded from your direct model?

MR. SOBOL: Objection.

A. The variables that we discussed do not appear in my direct model, and the direct model as an aggregate time series

Page 598

model has different considerations in terms of what variables are appropriate to include.
BY MR. ROTH:
Q. And because you did not include any of the excluded variables just discussed in your indirect model, you did not expressly measure the impact of those variables on the sales of opioids in Cuyahoga or Summit Counties?
MR. SOBOL: Objection, asked and answered.
A. While that is tautologically true, it is the case, as I started when we were talking about omitted variable bias, that it's always possible to add more variable to a model, and that is not -- that is not good without limit.
BY MR. ROTH:
Q. Well, I understand you don't want to add variables forever, but at what point does the number of variables in an indirect regression render the regression unstable?
A. Well, it would depend on the correlation among those variables.

Page 599

(Whereupon, Deposition Exhibit Rosenthal-23, Case and Deaton Publication, was marked for identification.)
BY MR. ROTH:
Q. Okay. Let me mark as Exhibit 23 an article by Case and Deaton entitled Mortality and Morbidity in the 21st Century.
MR. ROTH: We're finding one for you.
(Comments off the stenographic record.)
MR. SOBOL: Sounds like a fairly narrow topic for a paper.
MR. ROTH: Why don't we take a quick break. We'll look for the copy.
THE WITNESS: Okay.
THE VIDEOGRAPHER: The time is 10:16 a.m., we're now off the record.
(Discussion off the record.)
THE VIDEOGRAPHER: The time is 10:16 a.m. We're back on the record.
BY MR. ROTH:
Q. That's pretty efficient.

Page 600

A. That was very efficient.
Q. So do you have the Case and Deaton article in front of you?
A. I do.
Q. And if you look at page 444.
A. These economics articles are very long.
Q. I think you cite this article in your report, do you not?
A. I think I do, yes.
Q. Okay. Page 444, there's a comment from a friend.
Do you see that?
A. I do.
Q. And that's Professor Cutler, who is a co-expert with you and your colleague at Harvard?
A. Yes, that's correct.
Q. And so if you look at his comments on the next page, 445, starting in the middle of the page where he's talking about the article, he says: Their overall suggestion is very much in the tradition of ?mile Durkheim: People despair when their material and social circumstances are below

Page 601

what they had expected. This despair leads people to act in ways that significantly harm their health. This may have a direct impact on death through suicide or an indirect impact through heavy drinking, smoking, drug abuse, or not taking preventative medications for conditions such as heart disease. At root is economic and social breakdown. This explanation is certainly correct.
Do you see that?
A. I do.
Q. And what variables in your indirect model address the despair points that Professor Cutler is talking about?
A. Professor Cutler and Case and Deaton, they're talking about mortality. They're not talking about the use of opioids.
Q. Well, except that he says that despair can lead people to abuse drugs.
A. Yes, but it's quite a bit different. So they're talking about the mortality effects, which go beyond the use of drugs.
As we've discussed somewhat over the last day and a half, the use of

Page 602

opioids in and of itself doesn't lead everyone to die from an overdose. There's tolerance and addiction, and all along that chain, there are different factors that may contribute to who actually dies of an overdose. So this -- this paper is really trying to get at the mortality results.

And moreover, the socioeconomic variables included in my model have much to do with this idea of the expected material and social circumstances, has to do with employment, whether people are in the labor force. All of those socioeconomic variables capture those factors.

Q. But you don't include any variable, for example, on the incidence of depression in the counties?

MR. SOBOL: Objection.

A. I do not include a variable on the incidence of depression. I have no reason to believe that that would predict opioid use.

BY MR. ROTH:

Q. You don't include any variable on the incidence of alcoholism in the

Page 603

counties?

A. I do not include a variable on the incidence of alcoholism, nor would I expect it to predict opioid use.

Q. You don't think that alcohol use is correlated with opioid use?

A. Whether individuals who are likely to use opioids have some of the same personal characteristics as those individuals, that may well be true. But my demographic and socioeconomic factors are also capturing those underlying issues that may be, according to this notion, that the economic status of people is really what's driving the addiction tendencies, and those are the variables that I include in my model.

Q. And similarly, you don't include any variable in your -- either of your regression models related to drug abuse in the counties?

MR. SOBOL: Objection.

A. If you think about my indirect model, predicting shipments to have drug abuse on the right-hand side would make very little sense if the shipments caused the drug

Page 604

abuse.

BY MR. ROTH:

Q. Well, there are drugs other than opioids in the world that are abused, right?

A. That may be true. Again, as a broader matter, the demographic and socioeconomic variables that I do capture in my model are essentially the way Case and Deaton look at this as well as these being the predictors of ultimately what contributes to mortality.

MR. ROTH: Okay. Why don't we take another quick break.

THE WITNESS: Okay.

THE VIDEOGRAPHER: The time is 10:21 a.m. We're now off the record.

(Recess taken, 10:21 a.m. to 10:34 a.m.)

THE VIDEOGRAPHER: The time is 10:35 a.m., and we're back on the record.

BY MR. ROTH:

Q. So sticking with your indirect model.

Page 605

A. Okay.

Q. So we talked about a couple of times now how because the ARCOS data is at the molecule level, you couldn't back out the Schedule III opioids; is that right?

A. That's right. In those two molecules that have a mix, right?

Q. And your report says you don't believe this impacts the model because it affects only less than 2?% of shipments, and then you further clarified actually that it's less than 1%.

Did I hear that right?

A. Right. So it's less than 2?% of shipments in those molecules -- I'm actually trying to look for the text. Do you have that paragraph?

Q. It's paragraph 83.

A. Okay, great. Thank you. Less than 2?% of the shipments in those molecules that have a mix of Schedule II and Schedule III, and that's hydrocodone and codeine, I believe, are the two molecules that are relevant.

Q. And did you test how removing

Page 606

all of the Schedule III opioids from the ARCOS data would impact your model?
A. I don't believe so, no. I mean, I assume what you mean is overremoving since in the ARCOS data I couldn't distinguish, but removing the molecules that have any Schedule III, is that what you're asking?
Q. Right?
A. Yeah. That, I did not test.
Q. And we established you used 1997 as your baseline, right?
A. That's correct.
Q. So I assume your assumption is that the relationship between demographic, economic and healthcare variables for 1997 holds for all future years?
A. That is the basic assumption of the indirect model in general, is that the cross-sectional relationships are stable, and just the variation in those variables changes over time.
Q. Do you know what the rescheduled Schedule III opioids were as a percentage of sales in 1997?

Page 607

A. When you say rescheduled, you're just talking about hydrocodone?
Q. Well, let me reask the question.
A. Sure.
Q. Do you know what the percentage of sales Schedule III opioids were in 1997?
A. If -- I'm sorry. I don't know that I understand the question because I know the answer to a version of that question, which I think is the relevant one.
The percentage of the included molecules that are Schedule III that I can't pull out is 2?%.
Q. In 1997?
A. In 1997, yes.
Q. Okay. What about the rest of the Schedule III, that later became Schedule II on the rescheduling, what was their percentage of sales in 1997?
A. So now we're talking about hydrocodone rescheduling?
Q. Correct.
A. I have not assessed that. Again, as we talked about yesterday, I've

Page 608

been asked to assume that hydrocodone should be included in my measure of impact for the whole period.
Q. And how would it affect the results of your indirect regression if the percentage of Schedule III molecules in the sales data changes over time?
A. I don't think it would affect the results. I mean, I think, again, to the extent that it has an effect, it's a -- it's a level effect.
For such a small quantum that's in my analysis, the Schedule III drugs, it's just next to impossible that it has any effect on the coefficients. It overstates the set of molecules, the number of MMEs, and that effect I know also is small. It's less than 1% of MMEs.
In terms of the rescheduling of hydrocodone, I haven't quantified that, so as I sit here, I can't tell you. Again, I believe if it has an effect and if it's deemed, for example, that hydrocodone should only be included when it was Schedule II and not when it was Schedule III, then those MMEs

Page 609

would just be backed out of the levels.
Q. Okay. If we look back at Table 5 on page 61.
A. Yes.
Q. How does the volume of MMEs that you derive from your indirect regression compare to the volume of MMEs you derived in your direct regression?
A. The total volume, because I'm looking at the large counties here, they're about two-thirds of the national total, so it essentially should be about two-thirds. Again, these are annual numbers and I use monthly numbers as inputs into my direct analysis.
Q. And when you say you're looking at the large counties, can you explain that?
A. Sure. The ARCOS data that I used for the indirect model is the large county sample, so these are counties with populations of 100,000 or more.
Q. So it's not limited to Cuyahoga and Summit specifically?
A. That's correct.
Q. How do the peaks in the MMEs

Page 610

compare between the indirect regression and the direct regression?
A. Do you mean in the but-for or in the actual?
Q. Well, in the -- looking just -- I'll be more clear.
In looking at Table 5, it looks like the highest volume of total MMEs is actually in 2011.
Do you see that?
A. Yes, I mean, 2010 and 2011 are very similar, but it is slightly higher.
Q. Right. And I'm just trying to square that with your direct regression which found that there was this era turning point in 2010 that resulted in a decline after that.
A. Well, let's have a look at when the peak MMEs are as opposed to when I estimate the erosion begins to happen.
So I'm just looking at Figure 2. So the absolute peak is in 2011, but if you look at 2010, again, it's just a bit below 2011. There's sort of a flat spot at the top of the curve there, so...

Page 611

Q. Okay. So in both regressions, the peak is actually in 2011?
A. Yeah, I think the peak is in 2011.
Q. And you agree, based on the results of your direct regression, that defendants' promotion for opioids had less effect after 2010?
A. According to my model, the incremental effect of promotion began declining in late 2010, yes.
Q. Is it the case that the majority of the conduct influencing the but-for number in your direct model occurred before 2010?
A. I'm just trying to think about what's the right way to answer that question. You're talking -- we're talking about the direct model now?
Q. Correct. Well, here's my sort of question. So you've got conduct over time, right?
A. Yes.
Q. Starting in '95, right? And we've got a growing stock of promotion.

Page 612

We've been around all those issues.
So is it fair to say that given the parameters of your direct regression, your but-for model is being more heavily influenced by the 1995 to 2009 details than later details?
A. It is true based on Model B that those earlier detailing will -- I mean, it has a longer time to compound effectively.
What the level of detailing is, as you know, it's sort of up and down, so it's not a strictly monotonic thing, given that there were periods where the level of detailing was lower.
But in general, the model suggests that earlier detailing, because it has longer time to contribute to sales, for a given unit will have a bigger effect on the total.
Q. And you have not run any regression model that attempts to show the effect of defendants' promotion beginning in 2009 on prescriptions of opioids after that time?
A. Well, my model incorporates the

Page 613

entire time period. I haven't separately run a model from 2009 forward. I don't think it would be appropriate to run a separate model. One could use my model to run a but-for scenario in the post-estimation sense.
Q. But the issue there, though, is that you still have all these details from '95 to 2009 in your model, which have continuing -- continuing impact after 2009?
A. Well, just to be clear, I'm not sure what your hypothetical is, but if I wanted to know for some reason only what impact detailing from 2009 or any other year was from the present, I'd use the same model, but I would say that actual and but-for promotion are equal up until 2009, so not attributing impact to those earlier details.
And then from that point on, then I would reduce the promotional stock by the amount of detailing that happened after that time, so that would be the right way, if for some reason one wanted to look at a shorter time period.
Q. And that's not an analysis you've done so far?

Page 614

A. It's not, although I mention in Table 3 that I could limit my analysis to different time periods like that.
Q. Okay. Table 5 is measuring annual estimates based on your indirect method on an aggregate basis, correct?
A. As per my assignment, I'm looking at aggregate impact in this model as I do in the direct model.
Q. And it does not measure the impact of any specific manufacturer's promotion, the indirect model?
A. Again, I have been asked to calculate the aggregate impact, and because there are spillover effects across manufacturers, I believe here, as I did in the direct model, that it is appropriate to look not one defendant at a time, but to look overall at the underlying issues.
Q. You don't have any Table 3 or related methodology for your indirect regression, correct?
A. I don't have a Table 3 for the indirect method because, of course, it's indirect, and Table 3, as we have talked

Page 615

about at length, generates a different set of but-for assumptions by treating promotion differently for the subset of defendants.
Q. And you don't have any IQVIA/IPS-type data for the indirect regression that you could use to generate an allocation the way you have for the direct regression?
A. Again, here, the promotion is not directly measured by nature, so that doesn't map to defendants in the way it did in the direct model. In -- and so I have not thought about -- again, because it was not part of my assignment, I have not thought about allocating this to defendants. I think the logical way to do so might be based on MMEs.
Q. But you can't actually allocate by MMEs in your indirect model either because the ARCOS data is at a molecular level, not at an NDC level?
A. While that is true, I have the IQVIA data for the same years that would allow me to say within a molecule what share is Purdue, et cetera.

Page 616

Q. So you'd have to use a different dataset mapped onto your indirect regression if you were to try to allocate the indirect regression across and between defendants?
A. If such allocation were necessary for whatever reason, I think that would be the best way to do it.
Q. But as we sit here today, you have not done that work and you have no opinion as to what that allocation would be in your indirect regression?
A. I have not offered an opinion on that matter as you can see in my report.
Q. Does your indirect regression exclude opioid shipments by the non-defendants?
A. No, the indirect method is the aggregate market, so it includes non-defendants, and hence, the reason to include that secular trend.
Q. So when we look at these excess shares, that's not just for defendants' promotion, but it's for all promotion?
A. These excess shares are

Page 617

analogous to the excess shares that are in Table 2, which is they are the excess share of opioid prescribing overall that is associated with the misconduct, and again, that's the relevant parameter that I need to pass on to Professor Cutler.
Q. And Professor Cutler didn't actually use your indirect regression in the body of his report; is that correct?
A. I think in the body of his report he uses the direct, and then he replicates with the indirect in the -- one of his attachments.
Q. And did you have any conversations with Professor Cutler about that decision to use the direct in his main analysis and address the indirect in an attachment?
A. No.
Q. Do you know whether Professor McGuire uses your indirect regression as an input to his analysis?
A. I do not.
Q. Did you have any direct conversations with Professor McGuire about

Page 618

your analysis and how it would translate into his analysis?
A. Yes, at some point.
Q. Okay. And you understand that there's an intermediate step between you and Professor McGuire that is Professor Cutler's analysis?
A. Yes. As a general matter, yes, I understand how these fit together.
Q. Okay. Let's turn to Section X on page 62.
So in Section X, the question you pose in the heading is Does a Theory of Undertreated Pain Explain the Growth in Opiate Prescribing.
Do you see that?
A. Yes.
Q. And you say in paragraph 90: As an alternative to the defendants' marketing as being the explanation for much of the rise in opioid prescribing in the United States, I understand that some have argued an alternative explanation that pain was previously undertreated and that the growth in opioid shipments is due either to

Page 619

the amount of pain in the United States increasing over time, or more likely to the amount of the opioids used to properly treat pain increasing over time.
Do you see that?
A. I do.
Q. And then you say in paragraph 91: To test this hypothesis, I note there is empirical research on the prevalence of uncontrolled pain among cancer patients and other patient groups that could help us understand how much of the growth in opioid shipments could, as a theoretical matter, even possibly be attributed to using more opioids to treat pain consistent with medical evidence.
Do you see that?
A. I do.
Q. Then you've got a footnote that cites to a few medical articles by Dr. Portenoy, Dr. Cleeland, Dr. Donovan, a Marks and Sachar article, and then I won't even attempt to say the name of the last author.
Do you see that?

Page 620

A. I do.
Q. And is there any other empirical research on uncontrolled pain that you reviewed in connection with your report that supports the statement in paragraph 91 I just read?
A. Obviously these are the articles that I rely on. My point here is simply to say that prior to the period of the alleged misconduct, people were writing about the concerns about uncontrolled pain for these particular areas, and I'm simply -- I'm not trying to be exhaustive about it; I'm just simply showing that there is documentation in the academic literature of these concerns.
Q. And academic literature, by that you're talking primarily about medical articles, correct?
A. Well, undertreated pain presumably is a medical issue.
Q. Right. And then in paragraph 91 you say, after the sentence I read: In this section I use epidemiologic data and a simple simulation approach to

Page 621

approximate the portion of the increased prescribing caused by the allegedly unlawful promotion could possibly be associated with using opioids to address ostensibly undertreated pain.
A. It seems like I'm missing a word there.
Q. Yeah, I think there's a typo, but I read that correctly?
A. Yes, you did.
Q. Okay. So in paragraph 91 you describe the simple simulation approach, which in paragraph 92 you describe as a thought experiment.
Do you see that?
A. Yes.
Q. How would the economic literature describe the type of analysis you're conducting in paragraph 10 of your -- Section X of your report?
A. Generally, simulation is the word that economists would use to describe it.
Q. And is simulation a peer-reviewed methodology?

Page 622

A. Sure.
Q. And what papers would I read to describe how to conduct a proper simulation in economics?
MR. SOBOL: This one.
A. Simulations are used in a whole variety of settings. In general, the cost-effectiveness literature uses simulation as a primary methodology.
BY MR. ROTH:
Q. Okay. As you sit here now, can you think of a specific economics peer-reviewed paper that uses a simulation approach akin to the approach you take in Section X of your expert report?
A. As I sit here, I couldn't come up with a citation for you. My -- my recall for article names is not that good, but this is -- this is a pretty common approach, particularly when it comes to looking at the effects of policies, proposed policies.
Q. Have you published any research yourself that utilizes the same type of simulation approach that you outlined in Section X of your expert report?

Page 623

A. I have a recent paper that simulates a policy proposal that would, in effect, tax companies that raise their prescription drug prices above either the CPI or some other particular threshold, so that uses a simulation approach.
Q. And if we look at Attachment A, which is your CV, can you show me which paper you're talking about?
A. Yeah, let me just see. It was just published this year, but I think it should be on there. Sorry, that's my other documents.
It's article 119.
Q. Article 119. Generic prescription drug price increases, which products will be affected by proposed anti-gouging legislation?
A. That's correct.
Q. Beyond that article in -- 119 that you just identified, can you think of any other peer-reviewed publications you've authored that utilize the same type of approach you outline in Section X of your report?

Page 624

A. There is another one. Let me see if -- I just need to figure out what year it was.
Article 34.
Q. It's helpful that you number things, by the way.
So that's State and Federal approaches to health reform: What works for the working poor?
A. That's correct.
Q. Okay. Anything beyond those two?
A. I think that -- well, actually, I mention cost-effective analysis, and the article 115 is a cost-effectiveness analysis that uses a microsimulation model.
Q. Cost-effectiveness of Financial Incentives for Patients and Physicians to Manage Low-Density Lipoprotein Cholesterol Levels?
A. That's correct.
Q. Okay. So now we have three. Any others?
A. As far as I know, those are the relevant articles on my CV. Again, a

Page 625

simulation is commonly used as either a whole analysis or as part of an analysis. Sometimes researchers will take parameters that they estimate and then use them to simulate a policy change.
Q. And you've said a couple of times now, it's used to simulate a policy change.
Can you explain what you mean by that?
A. Well, in the case of the last article that we just talked about that we undertook a randomized control trial of financial incentives for doctors and patients to control cholesterol better, and we took what we learned in that randomized control trial and said what would happen basically if employers were to adopt this widely or if health insurance companies were to adopt this widely, what would happen to cholesterol control and downstream healthcare expenditures that would result.
Q. And to do that, you used a simulation similar to the one you used in Section X of your report?

Page 626

A. Yes, it's based on the same premise. We have some epidemiologic data and then some information about the relevant behaviors, and in this case, the treatment patterns for the patients.
Q. And you call this analysis a simulation study or is there some other term I should be using?
A. I call it a simulation, and as you can see, I then call it a thought experiment.
Q. Yeah. And it's simple simulation and a thought experiment, so I wasn't sure which is best. We may use both interchangeably, if that's okay.
A. Sure.
Q. What is the appropriate methodology in economics for conducting a simulation study such as the one that you have in paragraph 10 of your report?
A. Well, again, as I mentioned, a simulation generally involves some relevant population and then some behavioral parameters. And, I mean, the context will vary.

Page 627

In other contexts, we're looking at patients and their health behaviors. Simulations are frequently done around tax policy, so the relevant behaviors have to do with labor supply, for example.
And I do call this a simple simulation here because the only parameters I'm looking at are treatment patterns.
Q. If I wanted to find some peer-reviewed treatise or article that told me what the appropriate methodology is for a simple simulation such as the one you conduct in Section X of your report, where would I look?
A. I am not sure that there would be a single treatise. I think to the extent that there are methodological frameworks, I think they're likely context specific.
Q. So to figure out what the appropriate generally accepted economic methodology is for a simulation, I would have to review a bunch of articles that run simulations and determine the best approach myself?
A. I don't know if there's a

Page 628

single methodological paper that would apply here.
Q. Okay. So back to paragraph 91 --
A. Okay.
Q. -- you say at the end of the paragraph: In this section, I use epidemiological data and a simple simulation approach.
We talked about that.
And then the rest of the sentence says: To approximate the portion of the increased prescribing caused by the allegedly unlawful promotion -- I think you meant "that could possibly be associated."
A. Yes.
Q. Okay. So when you say promotion that could possibly be associated with using opioids, as we discussed, you're not a medical doctor, right?
A. That's correct.
Q. So you're relying on plaintiffs' medical experts to tell you what those parameters should be?
A. That's correct, in part, yes.

Page 629

Q. You did not make any independent assumptions about the type of patients that could have benefited medically from using opioids?
MR. SOBOL: Objection.
A. I -- as you can see and will note I talk about, I cite to a number of guidelines and articles, and I rely on plaintiffs' clinical experts to validate my assumptions.
BY MR. ROTH:
Q. Right, but since you're not a doctor, when you read the guidelines and articles, I take it you took direction from either a doctor or from counsel about what to take out of those articles?
MR. SOBOL: Objection.
A. Yes, that's correct.
BY MR. ROTH:
Q. Okay. And you don't have any medical expertise that you would need to make your own independent assumptions about the type of patients that could benefit from using opioids?
A. I am not a medical expert.

Page 630

Q. I want to look at paragraph 94. So towards the bottom of that paragraph, you say: Note that because I am not documenting the diagnoses and dosing associated with actual uses of opioids, I am not able to calculate how much of the increased use of opioids during the period in which the alleged misconduct occurred was in fact for clinically appropriate indications, dosages and durations.

Did I read that correctly?

A. You did.

Q. And that's similar to what we discussed yesterday. None of your analyses attempt to parse out whether the excess MMEs you identified were for medically appropriate uses?

A. Yes. Again, here I'm trying to calculate this maximum, just say let's just assume that, in fact, some portion of this growth is driven by better treating cancer patients, how much could that possibly be? But I have not been -- I do not have diagnosis codes that would allow me to precisely capture that in the data.

Page 631

Q. Do you know whether data with diagnosis codes for Cuyahoga and Summit County exists that you could use to do an actual analysis?

A. I don't know about whether data are available for Cuyahoga and Summit Counties specifically, no.

Q. And I read the sentence that I just took from paragraph 94 which you have emphasized a few times with italics as a limitation on your analysis, correct?

A. It's a kind of a limitation. It's just a really important clarification because I would not want someone reading my report to interpret the numbers that I've simulated to be actually representative of how prescriptions were -- you know, according to what diagnoses prescriptions were written.

So it's not really a limitation. The purpose of my analysis is to do something different, but it should not be interpreted as showing how much was actually used to address cancer pain.

Q. Your simulation is a hypothetical analysis based on assumptions

Page 632

you made from plaintiffs' experts' explanation of appropriate uses as opposed to a factual assessment of which prescriptions were medically necessary?

A. Yes. I mean, it is based on a set of facts, but it does not compute the share of prescriptions that were actually used for these indications.

Q. So let's look at kind of the foundational assumptions you've got in paragraph 92.

A. Okay.

Q. You say first: I conduct a thought experiment that allows me to calculate, in scare quotes, upper bound of how much of the growth in MMEs could be attributable to more intensive pain management for patient groups that according to plaintiffs' experts could have benefit from treatment of -- with opioids.

Do you see that?

A. Yes.

Q. And then you say: All of the underlying assumptions in this section have been developed in reference to the opinions

Page 633

of the plaintiffs' clinical experts, including Dr. Schumacher and Dr. Parran.

Do you see that?

A. Yes.

Q. Are there any plaintiffs' clinical experts who you rely on that are not Dr. Schumacher and Dr. Parran?

A. Not specifically that I rely on, no.

Q. Okay. I just was confused, because you say including, but you only named two of them, so I didn't know if there was someone else that's missing here.

A. I understand that there are other clinical experts. These are the clinical experts that I rely on.

Q. Did you review or rely on Dr. Ballantyne's report?

A. I did not, no.

Q. Are you aware that plaintiffs have withdrawn Dr. Parran's expert report?

A. I was not aware of that, no.

Q. Do you know which of the assumptions you made based on Dr. Parran's report in this section of yours?

Page 634

A. I don't believe any of the assumptions were solely based on Dr. Parran.
MR. ROTH: And so the record is clear for the reporter, we're actually talking about Parran, P-A-R-R-A-N, who is actually different than Perri, P-E-R-R-I. And Schumacher is S-C-H-U-M-A-C-H-E-R.
BY MR. ROTH:
Q. Okay. So based on the opinions of Dr. Schumacher and Dr. Parran, you next set forth the assumptions you make about what could possibly have been an appropriate medical use in paragraph 92?
MR. SOBOL: Objection.
A. Yes, I put forth those three categories of conditions that I understand have clear benefit from opioids.
BY MR. ROTH:
Q. Okay. So the first category is short-term treatment of severe acute pain, e.g., trauma or postsurgical pain, end-of-life pain/hospice care and cancer pain from active malignant disease.
A. That's right.

Page 635

Q. The second category you list based on Dr. Parran and Dr. Schumacher is actually sort of a noncategory, right?
A. Yes.
Q. Which --
A. Again, I'm sorry to interrupt you. Please finish.
Q. What you say in (ii) is: Chronic opioid therapy is not recommended for most common chronic pain conditions, defined as moderate to severe pain lasting beyond 60 to 90 days, including low back pain, centralized pain such as fibromyalgia and headache pain.
Do you see that?
A. I do.
Q. And we'll talk about this in a minute, but you actually exclude that from your thought experiment?
A. That's correct.
Q. And then the third category which is included is less common chronic pain conditions such as pain from advanced multiple sclerosis, sickle cell disease, pain following spinal cord injury and paraplegia

Page 636

or post-herpetic neuralgia, which comprise a small percentage of chronic pain patients and for which opioids may be considered a third-line therapy?
Do you see that?
A. I do.
Q. And actually, really, the only ones you include in your thought experiment are Romanette (i), which are trauma or postsurgical pain and cancer pain?
A. Yes, just -- I was going to just clarify. In this section in paragraph 92, I'm summarizing what I understand the opinions of the clinical experts have put forward in terms of appropriate uses broadly, and you're correct that when I go to implement my analysis, I'm focusing really on section (i), and I try to explain why.
Q. Okay. And we'll get there.
A. Yeah.
Q. So when you read plaintiffs' medical experts' reports, what you gleaned from those reports was that the only conditions they believed opioids are

Page 637

indicated properly to treat are those conditions listed in paragraph 92?
MR. SOBOL: Objection.
A. When I read those reports, I gleaned everything that I said in that -- in that extremely long sentence, which is a little more nuanced than I think what you just said.
BY MR. ROTH:
Q. Do you know whether plaintiffs' medical experts' positions regarding the proper indication of opioids today were the prevailing medical guidelines for use of opioids from 1995 to the present?
MR. SOBOL: Objection.
A. I am probably not the person to best characterize that, but I have looked at some of those guidelines, and I also have read the complaint, and I know that plaintiffs intend to prove that part of the misconduct influenced guidelines that were broader than these opinions.
So I believe by extension it must be true that there are guidelines from that period that suggest that it is safe to

Page 638

use opioids for things like chronic pain.
BY MR. ROTH:
Q. And you also understand that medical guidelines are not static, correct?
A. I understand that medical guidelines are not static.
Q. I mean, as a healthcare economist, I'm sure you've studied lots of drugs where indications and warnings and appropriate uses change over time?
A. Well, more specifically, I know in this case that there were updated guidelines issued.
Q. But in your thought experiment, you're imposing plaintiffs' experts' 2019 framework on opioid use from the entire period from 1995 to the present?
A. I think you mistake the purpose of my thought experiment. It is not to say what would happen if we imposed 2019 beliefs by these clinical experts, but rather to say in a world in which there was no misconduct, to what extent might the appropriate -- sort of appropriate efforts to address undertreated pain have led to similar

Page 639

patterns.
Q. So if I understand you then, your simulation is predicated on plaintiffs proving that the existing medical guidelines between 1995 and today were wrong as a result of defendants' misconduct?
A. Well, I think that you're giving a legal interpretation to my analysis that I'm not really in a good position to judge.
What -- the purpose of my analysis is to examine whether there might have been legitimate clinical drivers of the increase in opioids that could have explained a similar pattern of growth.
Again, as I understand it, defendants in related matters have said, you know, physicians began using opioids more heavily in the 1990s because of the recognition that pain was undertreated, so I'm simply examining that premise.
Q. But if your premise is to try to understand whether there were legitimate clinical drivers, why would you not use the clinical standards in existence at the time

Page 640

of prescription?
MR. SOBOL: Objection, asked and answered.
A. Those clinical standards are influenced by the misconduct.
BY MR. ROTH:
Q. So that goes back to my question.
An underlying assumption of Section X, your simulation analysis, is that plaintiffs can prove that defendants' misconduct influenced the extant clinical standards from 1995 until the present?
MR. SOBOL: Objection, asked and answered.
A. Again, I think that you're -- you're putting a sort of liability interpretation on this that -- that -- this is not a but-for analysis. You sound like you're describing it as a but-for analysis.
It's a thought experiment that says what if we use opioids to perfectly treat the patients that we know can be safely and effectively treated, what would that look like in comparison to the growth that we

Page 641

actually saw.
BY MR. ROTH:
Q. It's a thought experiment that says if the plaintiffs' experts are right about what opioids can be used for, then this shows how prescriptions compare to what they say opioids should be used for?
MR. SOBOL: Objection.
A. The thought experiment does depend on the assumptions about which groups could be appropriately treated. That is correct.
BY MR. ROTH:
Q. Put another way, your thought experiment does not measure opioid usage against the existing clinical standards in place at any point in time?
MR. SOBOL: Objection.
A. The thought experiment measures the level of opioid use that would have occurred -- sort of the highest level of opioid use that would have occurred according to what I believe plaintiffs' experts intend to prove is appropriate.
It is not based on any

Page 642

individual set of guidelines. As I mentioned, I am relying on clinical experts' opinions in order to identify these groups, and so it's not based on a set of guidelines.

The treatments -- the treatment patterns do come from some guidelines that I'm sure we will talk about, but again, there -- I do -- I do some sensitivity analysis, but naturally, the specific parameters I choose, including the patient groups, do affect the analysis.

And the reason why I call it a thought experiment is this is not intended to say this is -- there's only one version of this, but instead, to say, well, look, I've picked these three important groups, and I've assumed that absolutely everyone gets treated, and -- and look how little of the growth in opioids that explains. If you want to add another 50%, it still explains very little.

BY MR. ROTH:

Q. And what would the basis be for adding 50%? Just rough justice?

A. If you thought for example that

Page 643

I was missing a group of patients or that my -- that dosing, in fact, could safely be 50% higher or that duration could be 50% higher.

Q. I forgot to ask you earlier when we were talking about your methodology. Have you utilized a simulation approach similar to the one in Section X of your report in other expert work that you've done? And feel free to take a drink.

A. I'm sorry, now I have the reverse problem.

Q. Let me reask the question because the transcript is not clear.

Have you utilized a simulation approach like the one in Section X of your report in other expert work that you've done?

A. In effect, any but-for analysis is a simulation. I usually call those simulations because they abstract from the actual world by changing some set of facts. Those are simulations.

There have also been simulations in my expert work, for example, in the AWP matter, the damages are basically

Page 644

calculated by simulation, assuming that instead of whatever markup was actually charged, that there would have been only a 30% markup, for example, on drugs.

So simulation is very commonly used as a damage analysis. Although that's not what I'm using it here for.

Q. Have you used a simulation outside of damages analysis in other cases as you do in Section X of your report?

A. I'm not sure whether I have.

Q. So because Section X is based on plaintiffs' medical experts' assumptions about appropriate use of pain, you do not calculate MMEs associated with treatments beyond what they include in your analysis?

MR. SOBOL: Objection.

A. Oh, I'm sorry. I'm not totally sure what you're talking about.

BY MR. ROTH:

Q. So we can go through paragraph by paragraph and see exactly what types of pain -- what types of opioid uses you permit based on their opinions.

A. Yes.

Page 645

Q. And we'll do that. But my question is a little different.

My question is because you limit yourself to what you glean from Dr. Schumacher and Dr. Parran are appropriate uses of opioids, you do not include other uses of opioids that might be appropriate under medical guidelines in your simulation of MMEs?

A. I think it's fair to say that I include the three categories of patients in my analysis, and by extension, I do not include others.

Q. And looking back at paragraph 92, you took from Dr. Schumacher and Dr. Parran that chronic opioid therapy is not recommended for most common chronic pain indications, correct?

A. That's what I understood, yes.

Q. You understand that opioids are indicated for and labeled for those uses?

MR. SOBOL: Objection.

A. I do know that in some cases they are labeled for chronic pain.

///

Page 646

BY MR. ROTH:
Q. So your simulation depends not only on showing that the medical standards in place at the time were wrong, but also that the FDA should not have approved opioid use for chronic pain?
MR. SOBOL: Objection, in part asked and answered, misstates her prior testimony.
Go ahead.
A. I would not agree that it depends on that. My analysis conducts this thought experiment on this group for which it is clear that -- to clinical experts, as I understand it, that opioids are appropriately used.
For chronic pain patients, I understand that the clinical opinions that are being offered by plaintiff experts are of this mixed form, as I show here, and so I do not include those patients in my analysis.
I don't believe that means the analysis has no utility if, in fact, there's some subgroup of patients for whom they are appropriate. But that's, in fact, captured

Page 647

in these opinions, and we'll go on to talk about what the implications are.
I think my results can be viewed in the context of the idea that there may be this small group of chronic pain patients who benefit from opioids.
BY MR. ROTH:
Q. And if you were to include any number of chronic pain patients for whom opioid use is appropriate in your simulation, that would increase the number of potentially appropriate MMEs and thus, decrease the gap between actual MMEs prescribed and your potentially appropriate number?
MR. SOBOL: Objection.
A. If you were to add to the number of patients and the number of MMEs, that would increase the total, yes.
BY MR. ROTH:
Q. Have you done any study or analysis as to what number of chronic pain patients might be an appropriate quantum to add to your potentially appropriate group?
A. So I don't believe that there's a single number that I've seen when I look at

Page 648

the clinical opinions, as I've summarized them here. They're more qualitative.
And when they refer to third-line treatment, I think that is a concept that would require understanding what percentage of chronic pain patients have tried and failed to use other therapies.
Q. So we saw yesterday morning, which feels like a long time ago, that Excellus Blue Cross Blue Shield in its guidelines still approves of the use of opioids for pain in some circumstances.
A. In its formulary, yes, I think that's right.
Q. Okay. And are you aware the CDC guidelines also approve opioid use for chronic pain in some instances?
MR. SOBOL: Objection.
A. I do believe the CDC guidelines -- and I'm not sure that I've seen the most recent ones, but the CDC guidelines do mention chronic pain as a use for opioids.
BY MR. ROTH:
Q. And in fact, Dr. Parran himself agrees that chronic pain may be clinically

Page 649

appropriate for some subset of patients?
MR. SOBOL: Objection.
A. I believe those opinions again which are nuanced here summarize that same conclusion that you've drawn, that for some small group of patients, opioids may be appropriate.
BY MR. ROTH:
Q. Yeah. And I can mark this, but I don't know if you just remember. I mean, I think he says in his report chronic opioid therapy for persons with chronic pain conditions is at most indicated in less than 10% of patients with chronic pain, and likely significantly fewer.
Do you recall reading that?
A. That sounds familiar.
Q. Okay.
A. Obviously that's -- less than 10% is a hard number to plug into a simulation.
Q. It's some nonzero number, and he's saying it's somewhere between zero and ten without really saying what it is, so I would agree with you.

Page 650

But you recall seeing that he didn't say it was totally impermissible?
MR. SOBOL: Objection.
A. He did not -- and I'll slow down. And again, I reflect that nuance in my description here.
BY MR. ROTH:
Q. You reflect it in your description, but you don't reflect any number of chronic pain patients in your simulation.
A. That's correct, I explicitly exclude them.
(Whereupon, Deposition Exhibit Rosenthal-24, CDC Guideline for Prescribing Opioids for Chronic Pain, United States, 2016, was marked for identification.)
BY MR. ROTH:
Q. All right. I'm going to show you what I'll mark as Exhibit -- no, I don't want this one. Sorry. She's been so good.
A. I know. She has a hard job reading your mind.
Q. I'm going to mark as Exhibit 24 the CDC guidelines for prescribing opioids

Page 651

for chronic pain from 2016. And are these the guidelines you recall reviewing?
A. Yes, I have reviewed the 2016 guidelines.
Q. And are there more recent guidelines than 2016?
A. I'm not sure. That's -- I was just allowing for the possibility because I think there are older guidelines.
Q. Right. And the older guidelines it's fair to say are likely more generous in terms of what they suggest is appropriate usage for opioids with respect to chronic pain than the more recent guidelines?
MR. SOBOL: Objection.
A. I don't recall.
BY MR. ROTH:
Q. Would you not expect that, given the information in medical journals, et cetera, about an increased sensitivity frankly just to addiction issues and opioids?
A. I guess it depends on what we're comparing it to. If we had guidelines from 1990 or 1985, I would expect them to be even more cautionary.

Page 652

Q. And have you reviewed the guidelines from 1980 or 1985?
A. I have not.
Q. Okay. So you don't know that for sure; you're speculating.
A. That's correct.
MR. SOBOL: You asked her to speculate to begin with.
MR. ROTH: I know, but now I need to make clear on the record that that's what she's doing.
BY MR. ROTH:
Q. Okay. So these are published in 2016, which is well into period three of your preferred direct regression, correct?
A. That's correct.
Q. And if you look at the summary on the first page, it says: This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care and end-of-life care.
Do you see that?
A. I do.

Page 653

Q. And do Dr. Parran or Dr. Schumacher include any appropriate use of opioids for palliative care?
A. Again, as I summarized their statements, they include -- they include virtually the same terms, and many of those palliative care patients of course are also cancer patients.
Q. And they include cancer patients who are not just in hospice in their description, correct?
A. That's correct. Cancer patients may be in hospice or not in hospice but at the end of life.
Q. And do you know how the journals define end of life?
A. Well, I think there are different ways of looking at end of life, and they vary by analysis. I think frequently the last 90 days of life are considered end of life, but I'm -- I don't know that that's a single way of thinking about it.
Q. And of course, a doctor who's an oncologist with a patient may not actually know at the time they're prescribing how

Page 654

close they are to the end of life to know whether they're within that definition, right?
A. I'd be really impressed if they did know.
Q. Yeah. I mean, we all have stories of relatives or friends who were given a month to live and magically lived three or four years with cancer.
MR. SOBOL: Objection.
BY MR. ROTH:
Q. Do you know people like that?
A. I don't, but I'm glad that you do.
The idea of end of life as you know in my analysis, I use the actual end of life for my simulation, but it may well be that some of those people died without getting an opioid treatment because their doctors were not ready to decide that they were at the end of life.
Q. And there may also be people who the doctor thinks is at the end of life that they give an opioid to who actually live longer than the 90-day window in the

Page 655

definition?
A. Yes. I think that that is less often the case, given doctors' general reluctance. It's sort of a well-known fact in health policy that doctors are reluctant to acknowledge that the end of life has arrived.
Q. But doctors may decide to treat a cancer patient with an opioid even if they don't believe that patient is near the end of life to treat their pain from the malignancy.
A. That may well be true, but again, in my simulation, I'm looking at patients who are actually at the end of life.
Q. Okay. And by looking at only patients who are actually at the end of life, you're undercounting cancer patients who may be appropriately treated with an opioid to address malignant cancer pain but are not yet at the end of life?
A. I will not be including those patients who are not at the end of life, and we can go back to paragraph 92 to see that, like chronic pain, my understanding of clinical experts' opinions about patients who

Page 656

are not at the end of life who are experiencing cancer pain is -- that the same challenges pertain to opioid prescribing in terms of tradeoffs between possible addiction risks.
Q. So looking back at the summary, it then says, after the first sentence: The guideline addresses, 1, when to initiate or continue opioids for chronic pain; 2, opioid selection, dosage, duration, follow-up and discontinuation; and 3, assessing risk and addressing harms of opioid use.
Do you see that?
A. I do.
Q. And these guidelines were developed by the CDC, correct?
A. Yes.
Q. The Centers for Disease Control.
A. That's right.
Q. And they were developed in 2016, well into sensitivity around opioid use, addiction and mortality?
MR. SOBOL: Objection, scope.
A. It is certainly true at that

Page 657

time period that the opioid epidemic had been recognized.
BY MR. ROTH:
Q. And then if you look at the introduction in the background section, the first sentence says: Opioids are commonly prescribed for pain.
Do you see that?
A. Yes.
Q. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses, including acute and chronic pain, received an opioid prescription.
Do you see that?
A. Yes. And I'm certainly familiar with that fact.
Q. So if 20% of patients are receiving opioids for pain, that's a fairly large population of people. Would you agree with that?
MR. SOBOL: Objection.
A. Well, yes. I mean, you're familiar with the litigation that we're all involved in, and that is the subject of this

Page 658

litigation.
So even in 2016, as prescribing rates have begun to fall, they are well above the levels that are -- were observed 20 years ago. So this is precisely the issue that we're talking about is that opioids are overused, according to clinical experts.
BY MR. ROTH:
Q. Well, they're well above the level of 20 years ago, but there have been a number of new drugs and generics that have entered the market over the last 20 years, correct?
MR. SOBOL: Objection.
A. Well, the fact that there are new drugs and generics does not mean that increased use is appropriate.
BY MR. ROTH:
Q. And the mere fact that use has increased over what it was 20 years ago in and of itself does not mean that all of that increase is inappropriate either.
MR. SOBOL: Objection, scope.
A. In my analysis, as I noted earlier, I'm not parsing the actual uses.

Page 659

And because that is not possible to do in the data, I instead come from the other direction, which is to say, okay, let's look at those uses which are not contested. How much of the growth could they possibly explain.
So if the allegations are true, my direct analysis shows a large percentage of prescriptions were caused by the unlawful conduct, and then from this other direction, it appears that the uses that the clinical experts in this matter for plaintiffs consider to be the most appropriate uses only account for a very small percentage of the total.
So the statements that you've made are sweeping statements. Mine are much more precise.
BY MR. ROTH:
Q. Put another way, if Dr. Parran and Dr. Schumacher and plaintiffs' opinions about the appropriate use of opioids were the prevailing medical standard, there would be an extremely small percentage of patients who currently receive opioids in our world that

Page 660

would receive them?
MR. SOBOL: Objection, scope.
A. Of course it depends on what you mean, if there's a certain path dependence, as I'm sure you're well aware. If we come in today and try to unwind prescribing, there are patients who are already addicted to opioids.
But if a world happened in which only the uses described by the clinical experts, plaintiffs' clinical experts were those that for which opioids were used, you're right, that we would see a dramatic reduction in opioid use. That is the entire purpose and conclusion of my analysis.
BY MR. ROTH:
Q. And if you look at paragraph 1 under the background section in this article -- in the guidelines, the last sentence says: Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the lack -- sorry, let me start over.
The CDC guidelines say: Rates of opioid prescribing vary greatly across

Page 661

states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication.
Do you see that?
A. I do.
Q. So if marketing is national, and all physicians are equally affected by marketing, what explains the geographic variation in prescribing the CDC is highlighting?
MR. SOBOL: Objection, scope.
A. Well, as we talked about before, and as you can see in the indirect analysis, there are county-level factors that explain variation in shipments.
BY MR. ROTH:
Q. My question was a little different.
This article is talking about variation in prescribing, and what I'm trying to understand is if marketing is national and all doctors are affected, how could it be that there is variation in prescribing on a

Page 662

geographic basis?
MR. SOBOL: Objection, scope.
A. There -- prescribing and shipments are not different things. They're the same thing. The shipments result from prescriptions. And there are different baselines in different geographic areas, different baselines in terms of the level of use, in terms of all of those socioeconomic and demographic factors.
THE WITNESS: I hope you can't hear that on the tape.
A. So that variation exists, and then if a national promotional campaign will have different effects based on the underlying area characteristics.
BY MR. ROTH:
Q. And the CDC highlights that there's a lack of consensus among clinicians on how to use opioid medication.
Do you see that?
A. I do see that.
Q. And again, that means that promotion alone is not driving some consensus view as to the efficacy and safety of

Page 663

opioids?
MR. SOBOL: Objection, scope.
A. Well, I'm not sure how you derive anything from this about promotion. The fact that there's a lack of consensus among clinicians does not mean that promotion hasn't driven this increase in the aggregate. There may well be variation among clinicians in the extent to which they've responded to that promotion, but again, in the aggregate, that's really what my analysis is about, is what is the total.
There may be variation across areas and across physicians, and still the question is sort of what has happened to the overall growth over this time period.
Q. How much aggregation do you need to do to show that promotion has an overall growth effect?
A. I'm not sure I understand your question.
Q. Well, we seem to be agreeing that at a physician level there could be variation in the effect of promotion, right?
A. There can be variation at a

Page 664

physician level. That doesn't mean -- my point was that physicians may start in different places, they may be -- they may have a bigger effect because they have more patients of a particular type, but -- but still, there's a total effect.
And again, in this matter as I understand it, the court needs to know what the whole effect is, and the fact that it may be smaller for one physician and larger for another is -- does not seem relevant as I understand it to the task of proving impact.
Q. Understood. But even when aggregated up to a geographic level, the CDC is highlighting a lack of consensus among clinicians, and I agree that marketing may not affect all doctors equally, but your model seems to suggest that everyone is equally affected by marketing.
MR. SOBOL: Objection, asked and answered.
A. You misunderstand the nature of an aggregate model. Again, I calculate an average effect. I do not assume that there's no variation in that average.

Page 665

BY MR. ROTH:
Q. Right. So that gets back to the question I asked three questions ago.
How much do you need to average? How far up the chain do you need to go? It's not at the doctor level, it's not at the geographic level. Where do you start seeing the aggregative effects overcome variation in the effect of promotion?
A. I'm sorry, I don't mean to laugh, but that is just a very strange idea.
So anything you average over has variation. So at any level the average captures variation. And again, what I'm interested in here is the aggregate effect, and so I have looked at that effect. If one were interested in ascertaining something about variability, then you would disaggregate the data.
But the -- every average contains some kind of variation unless it's not a very interesting average of things that are exactly alike.
Q. Let's look at page 3, the top paragraph on the left side says:

Page 666

Professional organizations, states and federal agencies, e.g., the American Pain Society/American Academy of Pain Medicine, the Washington Agency Medical Directors Group and the U.S. Department of Veteran Affairs/Department of Defense have developed guidelines for opioid prescribing.

Do you see that?

A. I do.

Q. And why do you think the Department of Veteran Affairs and Department of Defense has their own guidelines for opioid prescribing?

MR. SOBOL: Objection, scope.

A. Because they provide medical care or reimburse medical care for active duty -- what is the general word -- military, active duty military as well as veterans.

BY MR. ROTH:

Q. And then it says: Existing guidelines share some common elements, including dosing thresholds, cautious titration and risk mitigation strategies such as using risk assessment tools, treatment agreements and urine drug testing. However,

Page 667

there is considerable variability in the specific recommendations, e.g., range of dosing thresholds of 90 morphine milligram equivalents a day to 200 morphine milligram equivalents a day, audience, e.g., primary care physicians versus specialists, use of evidence, e.g., systematic review, grading of evidence and recommendations and role of expert opinion, and rigor of methods for addressing conflict of interest.

Do you see that?

A. I do.

Q. And then it says: Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

So not only is there regional variation, but actually in the medical community, there's variation in prescribing standards for opioids?

MR. SOBOL: Objection, scope.

BY MR. ROTH:

Q. Do you agree that's what the

Page 668

CDC is saying?

MR. SOBOL: Objection, scope.

A. I think what the CDC is saying is that both across professional organizations -- I think it's a little broader than the medical community, since we're talking about agencies, that guidelines vary.

BY MR. ROTH:

Q. And I assume, based on your testimony throughout the last two days and this sort of contagion effect that Dr. Perri coined, your view would be that those medical associations are influenced by the effect of manufacturers' promotion as well?

A. I believe that plaintiffs specifically point to those influences in the complaint, and so, of course, that is -- between that and Dr. Perri's report is where I get my information. I have not made an individual assessment of this.

Q. Again I ask, if promotion is this unifying thing that influences all physicians equally, why is there a variability in the guidelines that

Page 669

professional organizations come out with for the prescription and use of opioids?

MR. SOBOL: Objection, mischaracterizes prior testimony.

A. As I noted earlier, promotion will have effects that are different for different physicians, no doubt different professional organizations.

Because it has the same direction of effect doesn't mean they all start in the same place or end in the same place, and so guidelines vary across a number of seemingly well-accepted clinical areas.

BY MR. ROTH:

Q. And the effect that promotion has, if any, on those guidelines will also vary?

A. The effect of promotion on those guidelines may also vary.

Q. And neither your direct nor indirect regression models do anything to measure the effect of medical guidelines on the prescription and use of opioids?

MR. SOBOL: Objection, asked and answered, mischaracterizes prior

Page 670

testimony.
A. The direct model, Model C, includes events for guideline dissemination, and -- and the guidelines are not included in the indirect model.
BY MR. ROTH:
Q. In Model C you've got the five events -- I don't remember all of them from memory. I probably will soon. I think one was the joint consensus statement, which was a guideline; is that right?
A. Yes, that's correct.
Q. Were any of the others guidelines?
A. The JCAHO standards are similar to guidelines in they set expectations for hospitals.
Q. Okay. And beyond those two, I don't think the other three events were guideline related.
A. Federation of State Medical Boards, those, I believe, are focused really on liability issues.
Q. Did you consider using, for example, the CDC guidelines or other

Page 671

guidelines to test how your model would respond in Model C?
MR. SOBOL: Objection.
A. The CDC guidelines come out in 2016, which is at the tail end of my data, and as we talked about before, it was apparent to me when I included five events that simply adding more effects was not going to improve the performance of the model.
BY MR. ROTH:
Q. It wouldn't improve the performance of the model, but it might show that the performance of the model didn't stand up once you added multiple events?
MR. SOBOL: Objection, asked and answered.
A. Well, the fact that a model with more events did not look good doesn't mean the model that I chose with no events was unreliable.
BY MR. ROTH:
Q. If you look at page 17 of the CDC guidelines --
A. Incidentally by the way, I didn't try that model, so I don't know what

Page 672

it looks like.
Q. Good clarification.
So page 17 is the start of a long discussion of 12 bolded points that clinicians should consider when prescribing opioids for chronic pain.
Do you see that?
A. I see -- let's see.
Q. There are headings in between --
A. Yes.
Q. -- so it's hard to track, but --
A. I see 12, yes.
Q. Okay. And again, this is not consistent with the view that no patients should ever receive opioid for chronic pain; it just highlights thing clinicians should consider before prescribing opioids for chronic pain?
MR. SOBOL: Objection, scope.
A. I don't believe anywhere in my report I summarize a clinician's opinion that no patients should receive opioids for chronic pain.

Page 673

BY MR. ROTH:
Q. I don't want to go through all 12, but I do want to ask about a couple.
A. Okay.
Q. So if you look at page 21.
A. Sure.
Q. Number 4 in the section Opioid Selection, Dosage, Duration, Follow-Up and Discontinuation.
Do you see that?
A. I do.
Q. It says: When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting, ER/LA, opioids, recommendation category A, evidence type, 4.
Do you see that?
A. I do.
Q. So the CDC is making some distinction between immediate-release and extended-release long-acting opioids.
Do you agree with that?
A. Yes, this recommendation specifically applies to immediate-release

Page 674

opioids, yes.
Q. And your models don't distinguish between immediate-release or extended-release opioids or any other distinguishing characteristics of opioids other than calibrating them based on MMEs?
MR. SOBOL: Objection.
A. In order to accurately capture the impact of the alleged misconduct, I include all forms of opioids, including short- and long-acting.
My model is intended to capture any spillover effects, and to the extent that marketing of one product affects use of another, it appropriately captures those spillover effects.
To the extent that marketing does not have spillover effects, they won't be detected inappropriately.
BY MR. ROTH:
Q. Number 5 says -- it's on page 22 -- when opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids of any

Page 675

dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to greater than or equal to 50 MME per day, and should avoid increasing dosage to greater than or equal to 90 MME per day, or carefully justify a decision to titrate dosage to greater than or equal to 90 MME per day.
Do you see that?
A. I do.
Q. So the CDC seems to be making a distinction in terms of potency with respect to the clinical guidelines.
MR. SOBOL: Objection.
A. Okay.
MR. SOBOL: Scope.
A. So they're talking about effective dosing.
BY MR. ROTH:
Q. And again, that's not something you control for in your regression models?
A. That doesn't make any sense as something to control for. Again, I appropriately used the number of MMEs as the dependent variable, so that is recognizing

Page 676

that the number of MMEs is what is clinically relevant when it comes to ultimately the harms that Professor Cutler looks at.
And so I do, in fact, capture MMEs in my model.
Q. Okay. So we had an extended conversation yesterday about the depreciation factor, and you said it was justified because opioids are addictive and patients need to titrate up.
Do you remember that?
A. Yes.
Q. How does that assumption hold in light of the CDC's clinical guidelines suggesting that physicians should maintain patients on lower doses?
MR. SOBOL: Objection, form.
You can answer.
A. Are you suggesting that because the 2016 guidelines warn physicians on not increasing doses that none of that happened during the period of my analysis, 1995 to 2018?
BY MR. ROTH:
Q. Well, I'm asking the questions,

Page 677

but I'm just suggesting that you didn't account for it in your analysis, including after 2016 when these guidelines were published.
MR. SOBOL: Objection.
You can answer.
A. I would respectfully disagree with that characterization. My analysis incorporates exactly that, and yesterday we had a brief conversation about a chart that shows the increasing MMEs per prescription that demonstrate that doctors were clearly not following this guideline.
This is precisely the concern with the opioid epidemic is that dosing has continued to ramp up, and, you know, whether or not this guideline has influenced physicians to date, there's certainly plenty of evidence that there were increased dosing patterns over time for patients who were on opioids.
MR. ROTH: Okay. Why don't we stop for a minute. I don't know if lunch is here, but this would not be a bad time to break since it's around

Page 678

noon.
THE WITNESS: Sure, that's great.
THE VIDEOGRAPHER: The time is 11:54 a.m. We're now off the record.
(Recess taken, 11:54 a.m. to 12:30 p.m.)
THE VIDEOGRAPHER: The time is 12:30 p.m. We're back on the record.
BY MR. ROTH:
Q. All right. So I'd like to go kind of component by component through your simulation on appropriate use, if that's okay.
A. Okay. Great. I'll just get to the right section.
Q. Paragraph 95 is the start of the cancer pain section.
Are you there?
A. Yes.
Q. So you say: The first group of patients with potentially undertreated pain includes cancer patients at the end of life/ in hospice. I use epidemiologic data on cancer deaths in each year to identify the

Page 679

size of this population.
And that's consistent with what you said earlier, you just looked at end-of-life cancer patients, correct?
A. That's correct.
Q. Why just limit to end-of-life cancer patients as opposed to patients with other malignancy associated with cancer?
A. Sure. As I understand clinical experts' opinions and just some of the basic risks of opioids, that, of course, people at the end of life, the -- any concern about addiction is attenuated because of the fact that their timeline is short.
And so those patients are distinct from patients who may have continued use and continued life beyond -- beyond the point of malignant cancer pain.
Q. So -- but in paragraph 92 when you summarize Dr. Schumacher and Dr. Parran, you separately refer to end-of-life pain, hospice care and cancer pain from active malignant disease.
Do you see that?
A. Yes, that's correct. So again,

Page 680

in footnote 121, I explain a bit there. I say I do not attempt to separately identify these patients for lack of complete data and because I understand there's more clinical nuance, so again, that doctors will need to trade off addiction risks in those patients as I understand the clinical opinions.
Q. Okay. So your thought analysis just includes end-of-life cancer patients, not other cancer parents with malignant disease for the reasons you say in footnote 121?
A. Yes, that's correct.
Q. Why do you not include other patients in hospice beyond cancer patients?
A. Yes, again, a two-part -- and I'm trying to see exactly what I say in footnote 121. But many patients in hospice are in fact cancer patients. Cancer patients are really the group of patients for whom hospice was originally designed, and while it has spread to other reasons that people are facing the end of life, cancer patients are, particularly in the early years, I believe, based on the -- my general knowledge of

Page 681

hospice, the majority of those patients.
Q. Have you studied a breakdown of the demographics of hospice by diagnosis to know that that's true?
A. I know just from my knowledge of the area that cancer has been the condition around which hospice -- both hospice and really palliative care have been focused in the beginning, and it's a general health policy debate, the need to expand hospice and palliative care to other groups, so I understand that cancer is a dominant condition for those groups.
Q. You are aware that patients with other medical diagnoses than cancer may wind up in hospice?
A. Yes, I'm aware of that.
Q. Congestive heart failure patients could be in hospice, correct?
A. Yes.
Q. Or ALS patients, correct?
A. Yes.
Q. And we can play this game --
A. I am aware of that.
Q. -- with many conditions that

Page 682

are unfortunately terminal, but no matter, you only include the cancer hospice patients in your thought analysis.
A. Well, I include cancer patients at the end of life.
Q. Right. You make no attempt to capture other noncancer-diagnosed hospice patients at the end of life?
A. I do not. And again, as I note in footnote 121, I believe, my sensitivity analysis will likely capture those groups.
Q. Well, in footnote 121, you're actually just talking about -- yeah, okay. I see, patients dying from other conditions. Okay.
And then in order to calculate the amount of -- well, let me backtrack because I can't let this go.
So when you say your sensitivity analysis, that's truly just modeling a 50% increase in your parameters?
MR. SOBOL: Objection.
A. The sensitivity analysis is modeling a 50% increase, so that could pertain to a 50% increase in the populations

Page 683

treated.
BY MR. ROTH:
Q. And where did you come up with 50%?
A. In simulation analysis, people frequently use estimates to get at possible measurement error, which are inherently speculative. So this was to me a very generous speculation about how big the error could be.
Q. It's a statistical choice, it's not a choice based on any analysis of medical data?
A. It is a modeling choice, yes.
Q. Okay. And then in paragraph 96 you say: For my simulation I take a conservative approach and assume that 100% of cancer patients at the end of life need and want a high dose of oral extended-release opioids.
Do you see that?
A. I do, except you corrected my order.
Q. I transposed -- I think your order is fine, I just transposed it for some

Page 684

reason.
Then you say: This assumption is extremely conservative in light of plaintiffs' clinical expert, Dr. Parran's, opinion.
Do you see that?
A. Yes.
Q. And Parran's been withdrawn. Do you have any other basis for saying that it's extremely conservative to assume that all cancer patients at the end of life need and want a high dose of opioids?
MR. SOBOL: Objection.
A. Well, I think it's -- I'm not a clinician, so I -- I think it's unreasonable to assume that a hundred percent of patients want anything, particularly given the side effects of opioids unrelated to addiction, increased risk of death from respiratory issues, et cetera.
So I would say that a hundred percent must be conservative.
BY MR. ROTH:
Q. And then you say: For dosing, my baseline assumption is 80 MMEs per day,

Page 685

which is consistent with average dosing in cancer patients reported in public studies.
Do you see that?
A. I do.
Q. Then you cite the Haider Journal of Oncology article?
A. Yes, that's correct.
Q. Are there any other published studies you're relying on, or is that the one you're relying on?
A. That's the one I rely on, and as noted, those choices were reviewed by Dr. Schumacher and Parran.
Q. And I assume, since you're not a doctor, the Haider study was something that either Dr. Schumacher, Dr. Parran or counsel directed you to?
A. I believe that I identified that article.
Q. Okay. Spending time on PubMed?
A. I spend a lot of time on PubMed. As you know, the clinical literature and the health services research literature are quite overlapping. If you've looked at my CVs, I have -- have I published in an

Page 686

oncology journal? I believe I have.
Q. So we talked about dosing, which we'll talk about again in a minute, but then you say for duration, that you use the average duration of treatment reported for cancer palliative care as your baseline, which is roughly 64 days.
A. That's correct.
Q. And where -- that is based on the Carlson study, it looks like?
A. Yes, it is.
Q. Okay. And so in your thought experiment, if a cancer patient lives a year in excruciating pain, there would be no medically appropriate use for opioids for that patient?
MR. SOBOL: Objection.
A. Well, I'm not offering a clinical opinion here. I'm conducting an economic simulation based on clinical parameters that are identified from the literature and plaintiffs' clinical experts.
So I'm not saying one way or another whether someone who lives beyond those expectations should or shouldn't get an

Page 687

opioid.
BY MR. ROTH:
Q. So you're not making a medical judgment or a qualitative judgment, but you're still deciding not to include that patient in your potentially acceptable population?
MR. SOBOL: Objection. Excuse me. Objection.
A. The simulation again, it assumes that every single patient gets some opioid, and then assigns a typical payment based on the sources that I've cited. The length of stay there is an average, so unfortunately, we know that many patients do not actually know that they're dying more than a week or two before they die. As we talked about before, physicians tend to be reluctant to address those issues.
So I would imagine there are many patients who in fact would get this kind of opioid treatment for much less than the 64 days, and there may well be some that get it for more. But if the duration on average captures that, my simulation will reflect it.

Page 688

BY MR. ROTH:
Q. It's like with your other model, it's an average. So there are going to be people above and below the average with respect to treatment time?
A. And nonetheless, the aggregate will still be representative.
Q. You can average anything, right?
MR. SOBOL: Objection.
A. Well, if I'm trying to calculate a total, which is what I'm trying to do here, then the average is a sufficient statistic for that total, and so that's -- that's why I use it here.
BY MR. ROTH:
Q. Just so I understand it, though, obviously there's sample size issues when you average something, correct?
A. Sample size issues pertain to standard deviations, not to the mean, and here again, I'm using this simulation approach to show an average and not to characterize the variance around that.
(Whereupon, Deposition Exhibit

Page 689

Rosenthal-25, 2017 Haider et al Publication, was marked for identification.)
BY MR. ROTH:
Q. I'm going to mark as Exhibit 25 an article entitled Opioid Prescription Trends Among Patients with Cancer Referred to Outpatient Palliative Care Over a 6-Year Period.
Is this the Haider study that you cite in footnote 124 of your report?
A. It is.
Q. And that's the study you relied on to come up with the baseline assumption of 80 MMEs per day?
A. That's right.
Q. Okay. So if you look on the cover page, under Material and Methods, the last sentence says: Data collected included demographics, cancer type and stage, symptom assessment, performance status, opioid type and opioid dose defined as the morphine equivalent daily dose.
Do you see that?
A. I do.

Page 690

Q. And then in Results, it says: In 2010, median morphine equivalent daily dose before referral was 78 milligrams per day. However, by 2015, the morphine equivalent daily dose had progressively decreased to 40 milligrams per day.
A. I see that.
Q. And this study looks at the number of MMEs prescribed to 750 patients who were seen as new consultations at MD Anderson Cancer Center between January 1st and April 30th each year from 2010 and 2015?
A. That's correct.
Q. And this is the only article you rely on for your conclusion that the appropriate treatment is 80 morphine milligram equivalents per day?
A. Again, yes, this is the article where I found that dosing and referred it to the clinical experts for their input.
Q. And this dosing, again, is for patients who were at the cancer center's outpatient palliative care clinic, correct?
A. That's correct.
Q. It's not at a hospice facility?

Page 691

A. It was not.
Q. So you don't have any articles that you relied on to evaluate the appropriate dosage in MMEs given to end-of-life cancer patients at hospice?
A. This high dose estimate was the estimate that I found that was closest to what I was looking for. I think some of these patients may be at the end of life and some are not.
Q. And if patients are not yet at the end of life, would you expect their opioid dosing to be higher or lower than patients in hospice?
A. It may be, again, that this 80 number is lower. I don't know for sure. Again, why I do the sensitivity analysis by saying what if it were 50% higher, so not 80, but 120.
Q. And again, you're not a medical doctor, so beyond the Haider article, do you have any basis to say what an appropriate opioid dosage is in MMEs for a hospice patient?
MR. SOBOL: Objection.

Page 692

A. Again, I refer these assumptions to the clinical experts for them to validate or contradict them.
BY MR. ROTH:
Q. And did one of the clinical experts review this part of your report and give you feedback?
A. That review was done through counsel.
Q. Do you know which clinical expert reviewed your report and endorsed the 80 milligrams morphine equivalent for the daily dose for hospice patients?
A. I believe that both Dr. Schumacher and Dr. Parran reviewed this section of my report, specifically to look at the assumptions.
Q. If you look at e977 of the same article.
A. Sorry, you're still on there.
Q. We're still on Haider.
A. Sure.
Q. So on the second column, last paragraph, it says: Despite a robust dataset, there are several limitations to

Page 693

this study. First, patients were treated at a comprehensive cancer center where dedicated palliative care services are available. Hence, data from this single institution cannot be generalized to other clinical settings such as community-based programs.
Do you see that limitation?
A. I do.
Q. And is that something you considered when deciding this was the study to rely on?
A. Well, again, because I was seeking an estimate associated with palliative care, end-of-life care in particular, I don't think that limitation would pertain to my use of dosing from this study. I, of course, can't know what's in the authors' minds, but I think what they're talking about is about treatment patterns, and a cancer center may be different than less well organized cancer treatment.
Q. So you think when the authors say data from the single institution cannot be generalized to other clinical settings, they mean data from the single institution

Page 694

can be generalized to hospice patients?
MR. SOBOL: Objection.
A. That is not what I said, but, for example, they are looking at prescribing patterns across molecules and not just dosages, and so it may well be that the kind of prescribing over time that patients get in a cancer center is different.
The -- it's not immediately obvious to me why dosing in a cancer center would be different than dosing in -- outside of it. There may be some difference. It's always true that any article relies on a particular dataset, and they will all say that you can't generalize outside of that dataset.
BY MR. ROTH:
Q. And we've been over this, but you're not an oncologist, correct?
A. I'm not an oncologist.
Q. So to ascertain the differences between treatment in a cancer center versus hospice, you would just be speculating as to what that might be?
MR. SOBOL: Objection.

Page 695

A. Well, I am a health economist who has worked on cancer treatment as the subject of some of my research, so -- so yes, I don't know exactly what differences the authors had in mind, but I can make an informed speculation.
BY MR. ROTH:
Q. Informed speculation. That's a good one.
A. Yes.
Q. Is that more admissible than normal speculation?
MR. SOBOL: Sounds like to me.
THE WITNESS: Absolutely. Speculation with a Ph.D.
MR. SOBOL: Shouldn't have asked that.
BY MR. ROTH:
Q. So then if we look at paragraph 96, we talked about the duration, you said 64 days.
A. Yes.
Q. And you say you chose 64 days because it's just below the average number of days spent in hospice, which is 70.

Page 696

A. Well, I chose 64 days from another article. I didn't choose 64 as arbitrarily just below 70 days. I'm sorry if you read that sentence that way.
Q. Yeah. I mean, it says 64, which is just below the average number of days. I was trying to figure out why you didn't pick 69 or 68 or 70 itself.
A. I apologize for the lack of clarity. If you go back to footnote 125, the second article by Wachterman, et al.
Q. That one has 64 days?
A. That's the length of stay article, yes.
Q. And what did the Carlson article or the website you cite report as the average length of stay?
A. Right. So the 64 days comes from the Wachterman article. The 70 comes from the website.
Q. And why did you choose to credit Wachterman's article over the average from the National Hospice and Palliative Care Organization website -- or research, I should say.

Page 697

A. Sure. Because not every patient at the end of life is in hospice, so the -- the data in the Wachterman article are -- they -- sorry.
What I mean is not every patient in the second set of statistics has cancer, whereas the Wachterman article has a cancer subpopulation in it, so it's just more precise. They're very similar. The difference would be about a 10% difference.
Q. And I assume you'll tell me that that's captured in your 50% sensitivity analysis.
A. Well, that I can tell you, 10% is definitely less than 50%.
Q. And what did the Carlson article say the average length of stay was?
A. I actually don't recall looking at the length of stay in the Carlson article.
Q. Okay.
A. We can look at it.
Q. So now we're going to do math, which is a little dangerous for me, but we're going to try it.
So for one patient receiving

Page 698

end-of-life cancer pain, your two assumptions of 64 and 80 MMEs would get you to 5,120 MMEs?
A. Okay. I also can't do math without at least a pen.
Q. We have an iPhone, so let's try it.
A. Let's try it.
Q. This is the best deposition tool I've found. So 64 times 80 is 5,120.
A. Great.
Q. And so to calculate the total number of --
MR. SOBOL: How does she know you just didn't type in 5,120?
MR. ROTH: She can do it if she wants.
THE WITNESS: He has an honest face.
MR. SOBOL: Go ahead. Sorry.
BY MR. ROTH:
Q. To calculate the total number of MMEs associated with end-of-life cancer patients and hospice care for cancer patients, you multiplied the number of cancer

Page 699

deaths each year by 5,120 MMEs?
A. Yes. And just to be clear, you added "and hospice," but I'm very clear that I'm calculating treatment for end-of-life cancer patients.
Q. Right. Right. And you're not calculating at all for other hospice patients, which is the conversation we just had.
A. That's correct.
Q. And then where do you get the number of cancer deaths from, which of the datasets is that?
A. So that comes, excuse me, from the SEER data.
Q. Okay. So then the next category you calculate potentially acceptable MMEs for are patients with acute pain.
A. Uh-huh.
Q. And on page 66, and that's subdivided into trauma patients and surgical patients.
A. Correct.
Q. You don't consider any other type of acute pain?

Page 700

A. That's correct.
Q. So acute pain related to labor and childbirth would not be something that opioids are appropriate for?
A. Well, I'm not a clinical expert but I have actually not heard of people using opioids for labor pain.
Q. What about for pain associated with a cesarean section?
A. I'm not a clinician, so I think we shouldn't go there.
Q. What about for nontraumatic injuries causing acute pain? Those aren't captured by your analysis, correct?
A. Well, the -- we can go through in the technical appendix exactly which diagnosis codes are captured, so I'm not sure what you're referring to as nontraumatic injuries, but I think we should probably look at Attachment D.
Q. Okay. Let's do that. So where in Attachment D should we go?
A. Okay. Let's -- I'm starting on page -- as opposed to table -- D8 and working my way over, so for the clinical

Page 701

classification codes, we include our external causes of injury except for poisoning, overexertion, suffocation, adverse effects of medical care and drugs and other or unspecified causes.
Q. So let me pause there.
I assume you -- well, maybe I shouldn't assume. Let me just ask.
Why do you take out the categories of poisoning, overexertion, suffocation, adverse effects of medical care/drugs and other or unspecified causes?
A. Yes. I -- from what my understanding of the definition of appropriate uses under acute pain from the guidelines, these would not fit that category. And again, the underlying assumptions were shared with clinicians.
Q. This does lead me to a question I meant to ask you earlier.
Do your models, direct or indirect, include any opioid used to treat opioid use disorder, like naloxone or Suboxone, or were those taken out?
A. Those were taken out.

Page 702

Q. Okay. So in this analysis, you include all of the IDC-9 trauma codes except for the one specified on page D9?
A. That's correct.
Q. And apart from what you told me that the clinicians stated these would not be appropriate uses of opioids, you did not have any other basis for excluding them from your trauma numbers?
A. Well, I'm not a clinical expert, but I would say, on the face of it, the notion that opioids would be appropriate for adverse effects of medical care or drugs or poisoning is not something I would expect to be true, but I'm not a clinical expert, so I certainly use my judgment as a starting point.
Q. And certain opioids like Suboxone or naloxone might be, but are those taken out of this simulation as well?
A. They are not in my analysis.
Q. Okay. So back to paragraph 98.
A. Yeah, way back.
Q. So essentially, to measure the incidence of trauma, you use the data with

Page 703

the codes removed as specified in Attachment D?
A. That's correct.
Q. And you assume that a hundred percent of those patients are treated with opioids?
A. That's correct.
Q. And then you assume, according to paragraph 98, that each of these patients is treated with 30 MMEs of immediate-release opioids for three to seven days?
A. Correct.
Q. And for that statement, it looks like you are relying on a white paper from the American Academy of Emergency Medicine, and then the CDC guidelines that we reviewed earlier. Or is it just from the AAEM white paper?
A. I think they agree on these points.
Q. Okay. So let's look at the AAEM white paper, which I'll mark as Exhibit 26.
(Whereupon, Deposition Exhibit Rosenthal-26, AAEM White Paper on

Page 704

Acute Pain Management in the Emergency Department, was marked for identification.)
BY MR. ROTH:
Q. And this is the white paper you rely on as support for using 30 milligrams for three to seven days for trauma patients.
A. You've printed it very small, so --
Q. I did not, but someone did, and I apologize.
A. That's okay.
Q. Do we need a magnifying glass?
A. I'm not bothering your glasses. I'm going to hold it two feet in front of me.
Q. Well, then my next question is going to be particularly hard for you to answer.
MR. SOBOL: Is there a footnote on this?
BY MR. ROTH:
Q. I was going to ask where you see the 30 milligrams of an immediate-release opioid such as hydrocodone, because I didn't, but you may not be able to see even the text,

Page 705

so that might be a bigger problem.
A. Yeah, I'm -- I believe the guidelines -- some of the guidelines say start at the lowest possible dose. I'm not sure the 30 milligrams is in this guideline.
I believe that they all say use immediate release. Here, the second bullet under Upon Discharge From the ED: Emergency medicine clinicians should prescribe only immediate-release formulations at the lowest effective dose and for the shortest course, generally two to three days' supply.
I think the CDC guidelines say three to seven.
BY MR. ROTH:
Q. And is the 30 also in the CDC guidelines or is that somewhere else?
A. I don't think it actually is, and when I referred clinicians to this language, around the lowest effective dose, I believe that the 30 milligrams comes from getting a translation from clinical experts of what that lowest effective dose is.
Q. Okay. So that's clear now.
So now as I understand it, your

Page 706

assumption for 30 morphine milligram equivalents for trauma patients comes from Dr. Parran and Dr. Schumacher telling you that's what you should use?

MR. SOBOL: Objection.

A. There's some other guidelines that we'll get to around surgery that have some more specific doses, where I had those numbers to say, you know, should I use one of these. But they're not in this document. We'll get to them in the next section.

BY MR. ROTH:

Q. So for trauma, your dosage assumption comes from plaintiffs' experts?

A. It is -- yes. The -- the assumption, again, I did -- I used the guidelines to have that qualitative assumption, and I required assistance from clinical experts to make sure that I understood how to translate that.

But there were other guidelines that had some quantitative starting points, but not in these ones.

Q. And when you say clinical experts, that's Drs. Schumacher and Parran?

Page 707

A. That's correct.

Q. So for one patient receiving treatment for trauma in an emergency room setting, you assume 210 MMEs, which is 30 times the 7?

A. And which we do without a calculator, yes.

Q. That's true.

And so to calculate the total number of MMEs for all patients who visited an emergency room for trauma, you multiplied the patients in the data times 210?

A. The patients in the data times 210, yes.

Q. With the patients in the data being the page D9 description of which patients you looked at for trauma?

A. That's correct.

Q. Okay. So now let's talk about surgery, which is paragraph 99. So to identify patients treated with opioids related to surgery, you say the universe is patients who underwent surgery on either an inpatient or an outpatient basis.

A. That's correct.

Page 708

Q. And according to studies published around the time of the alleged misconduct, 41% -- sorry. Let me reread that.

According to studies published around the time the alleged misconduct began, 41% of postsurgical inpatients experienced moderate to severe pain.

Did I read that correctly?

A. Yes, you did.

Q. What do you mean by the time the alleged misconduct began?

A. Again, where I reference literature on undertreatment -- well, it's upset, so now I have to go back. I was looking for literature that predated the alleged misconduct, so that -- I just have to see where I first cite the Marks and Sachar paper in that footnote 117. So those are the studies that we talked about at the very beginning of this analysis.

Q. Is there any allegation that you're aware of that the alleged misconduct influenced the prescribing of opioids for surgical patients?

Page 709

MR. SOBOL: Objection.

A. I -- as I understand the misconduct, the misinformation would affect the treatment of patients being discharged from surgery like any other patients, yes.

BY MR. ROTH:

Q. So in your view, discharging patients from surgery with opioid prescriptions beyond those prescriptions that you classify as potentially acceptable would be something that plaintiffs are trying to recover for?

MR. SOBOL: Objection.

A. Well, it sounds like there's both a clinical and nonclinical opinion there, but again, remember this analysis is not decomposing actual use but trying to build up to a set of uses that according to clinical experts could have reasonably consumed opioid quantities over this period.

So again, we're not -- we're not sort of looking at what was done and parsing between appropriate and inappropriate. Just say, okay, well, there's going to be a set of people with surgery, and

Page 710

those people surely will have opioid use for some period of time. What would it look like if they all got treated.
BY MR. ROTH:
Q. So in paragraph 99, you again come up with 30 MMEs and seven days for surgery.
A. Yes, that's correct.
Q. So same as trauma?
A. Yes, the guidelines are quite similar.
Q. And for that conclusion that 30 MMEs each day is appropriate, you cite the MD Anderson Cancer Center Postoperative Pain Management Guidelines.
A. That's right. So that's the -- the document that I mentioned did have some quantitative benchmarks in it.
(Whereupon, Deposition Exhibit Rosenthal-27, MD Anderson Cancer Center Postoperative Pain Management Guidelines, was marked for identification.)
BY MR. ROTH:
Q. So let me mark as Exhibit 27

Page 711

the MD Anderson Cancer Center Postoperative Pain Management Guidelines.
And is this the document you were citing in your report?
A. It is.
Q. So it looks like this was approved, if you look at the bottom of the page, on October 30th, 2018.
A. Yes, that's correct.
Q. And are you aware that the algorithm used by MD Anderson to evaluate doses of pain management is what was used to come up with the dosage number? Strike that. That's not a good question. Let's just turn to page 3.
A. Okay. At some point, I would direct you to page 10, but we can go to page 3 first.
Q. Okay. We will get to page 10, I promise. It's in here.
A. Okay. Good.
Q. So it looks like they have sort of like a decision tree flow as to how they're going to come up with dosing for surgical patients, based on pain score.

Page 712

A. That's right.
Q. And it identifies different types of pain and the recommended treatment options.
A. Yes.
Q. So if you look at page 5, Appendix A describes the pain score, and it may or may not have highlighting on it.
A. It does. I appreciate the highlighting.
Q. Now you can see where we're going.
A. That's great.
Q. So if you look at page 5 in Appendix A, it says no pain is zero, mild is 1 to 3, moderate is 4 to 6 and severe is 7 to 10.
Do you see that?
A. I do.
Q. And then if you go back to page 3.
A. To page 3, okay.
Q. So for patients with a pain score of less than 3 who are not currently taking opioids, they recommend using

Page 713

nonopioids or weak opioids.
Do you see that?
A. Yes.
Q. And then for opioid treatment they refer to Appendix E, which is page 10, which we'll talk about in a minute.
A. Okay.
Q. Correct?
A. Yep.
Q. For patients with a pain score less than 3 who are currently taking opioids, MD Anderson recommends continuing the use of opioids and again refers to Appendix E.
A. Yes.
Q. For patients with a pain score greater to or equal than 4 and who are not taking opioids, MD Anderson recommends short-acting opioids.
Do you see that?
A. I do.
Q. And again refers to Appendix E, correct?
A. Yes.
Q. And then for patients with a pain score greater than or equal to 4 who are

Page 714

currently taking -- who are not currently taking opioids, MD Anderson recommends short-acting opioids -- we just did that one. Okay. Strike that. I'm getting tired.

For patients with a pain score greater than or equal to 4 who are currently taking opioids, MD Anderson recommends increasing the scheduled opioid dose.

A. Yes.

Q. All right. So now let's go to Appendix E on page 10. And we've conveniently highlighted this for you.

So if you look at hydrocodone --

A. Yes.

Q. -- it recommends 30 milligrams a day, right, 5 to 10 milligrams every six hours?

A. Yes. So 5 would be 20, right?

Q. Sorry, let me back up the truck. Okay. This is wrong.

A. Yes.

Q. So first we need to look at codeine, which is on the top of the page. So for codeine, it recommends 30 to

Page 715

60 milligrams.

Do you see that?

A. Yes. I did not consider codeine in the simulation per se, but go ahead.

Q. Okay. And now if we look at hydrocodone, it says for short-acting opioids, it's 5 to 10 milligrams every six hours.

A. Correct.

Q. Which if we do the math on that would be between 20 to 40 a day.

A. Yes. And 30 is right in the middle.

Q. Okay. And for long-acting opioids, 20 milligrams a day of Hysingla or 10 milligrams every ten hours.

A. I think in the flowchart we just looked at -- and again, according to clinical experts in this case, long-acting opioids are not recommended.

Q. Right. So it's 20 to 40 for immediate-release hydrocodone?

A. That's right, and 30 is in the middle of that.

Page 716

Q. It's the average.

A. It's the midpoint, it's the average. Yes.

Q. But then if you look at morphine, which is on the next page, that's also a short-acting opioid?

A. Yes.

Q. And it's 5 to 10 milligrams every four hours, which by math would get you 30 to 60.

A. Yes.

Q. So I guess what I'm trying to understand is how you get to 30 when one range is 20 to 40 and the other range is all -- is 30 to 60.

A. Sure. Again, that's why -- because the guidelines don't give one number, I referred this question to the clinical experts through counsel, and -- and was advised to focus on hydrocodone and was told that 30 milligrams was a reasonable baseline.

Again, assuming that there's some patients who will only get 20, some patients who will get more.

Q. So again, like with trauma for

Page 717

surgical pain, your decision to take 30 morphine milligram equivalents per day was driven by plaintiffs' experts' advice?

A. And it's grounded in these guidelines. And again, while the other guidelines that we looked at are qualitative in nature, as I understand the notion of starting with the lowest dose, that seems quite consistent with choosing 30.

Q. And so like with trauma, 30 times seven is 210, and then you multiply 210 for surgery with the number of surgical patients in the data?

A. That's correct.

Q. And then we should maybe just close the loop on this. So if we go back to the Attachment D.

A. Sure.

Q. Just to understand what data you're looking at for surgery.

A. Yeah.

Q. So it looks like page D10.

A. Oh, you're in -- it's page D14. I think we're on the same page. Aren't we?

Q. Page D10 talks about surgery.

Page 718

A. Oh.
Q. Page D14 is surgery in Cuyahoga and Summit.
A. I see. I was ahead of you. We'll get to that, I'm sure.
Q. Yes.
A. Yes. Yes. So Table D(b), which is also terrible labeling.
Q. Yes, so Table D(b) explains how you identified surgical procedures, and it says they're identified from the Area Health Resource File and the Health Resources & Services Administration data.
Do you see that?
A. Yes, that's correct.
Q. But then data was only available for 2005, 2010 and 2014?
A. That's correct.
Q. And so you had to linearly interpolate all the other values.
A. Yes, and as you can see, they barely change.
Q. But in any event, you only had data for three years, and so the rest of it was interpolated with the data that you had?

Page 719

A. I did interpolate.
Q. Okay. And so if you go back to the body of your report, Table 6, which is at page 70, essentially presents the math exercise we've been talking about, correct?
A. That's correct.
Q. It has kind of the cancer, trauma and surgical MMEs by year from 1995 to 2018 based on the inputs and assumptions we've been discussing.
A. Yes.
Q. And so according to Table 6, just looking at 1995, for example, there were 13,896,635,025 MMEs potentially clinically justifiable?
A. Yes.
Q. And then the next column is your sensitivity where you just multiply that number by 50%?
A. Correct.
Q. And so for 1995, your sensitivity shows 20,844 -- sorry, 20,844,950 -- start over.
For 1995, your sensitivity shows 20,844,952,537 MMEs were potentially

Page 720

clinically justifiable with the 50% increase?
A. Yes.
Q. And that's actually higher than the actual MMEs sold in that year?
A. That's correct. So that first number should be a negative.
Q. The first number should be a negative? I'm not sure I follow.
A. Well, of the total plus 50%, I guess the first -- the percentage there is of the -- of the unadjusted one, so it's correct, but --
Q. Yeah, it's correct. And what --
A. It actually would be negative if you did the plus 50%.
Q. Right. Okay. Thank you for that clarification.
A. It shows up in the chart more clearly.
Q. And actually, if we just look at '95 alone, even under your methodology, 75% of the actual MMEs sold -- or nearly 75%, would be potentially clinically justifiable?
A. Could have been accounted for

Page 721

justifiable use by -- by justifiable uses, right? So again, just to be clear that I'm not saying that 75% of actual uses were -- were delivered in that way, but they could have been.
The level of use was reasonably explained by this measure of need, if you would allow me to use that shorthand.
Q. And so if you use your potentially justifiable use methodology, including your 50% sensitivity analysis, it's not until 1997 that you start seeing more than a small departure from the actual MMEs sold?
A. Right. So in 1997, the actual is about 25% higher than the -- those justified by need.
Q. And then where is this actual MMEs sold number coming from? The IQVIA data it looks like? It says: Actual MMEs nationally from IQVIA, NPA, ARCOS, CDC.
(Clarification requested by the reporter.)
MR. ROTH: Okay. Sorry.
BY MR. ROTH:

Page 722

Q. The note on this chart is confusing to me because it says: Actual MMEs nationally from IQVIA, NPA, ARCOS and CDC.
A. The actual MMEs comes from IQVIA. The CDC part relates to the MME translation. As I sit here, I cannot think of a reason that the ARCOS data are used in the actual MMEs sold.
MR. SOBOL: Choice of drugs.
BY MR. ROTH:
Q. We may have found another errata.
A. No, it's more likely that I just can't remember that detail as I sit here.
Q. Okay. And then if you look at -- so you've got the chart, and then the next few paragraphs -- or the next paragraph, 102 on page 71, says --
A. Yes.
Q. -- The analysis described above can be applied at the county level. Table 7 shows comparable results for the bellwether counties.
Do you see that?

Page 723

A. Yes.
Q. And so then you've got a Table 7 with the counties.
How was the translation of the national analysis to the counties done?
A. So beginning with the number of patients in each category, there are county-level data available both on cancer deaths and from the Area Health Resource File, where the surgical cases come from, for the trauma patients they're allocated according to population.
Q. And who did that translation?
A. That would be my staff at GMA.
Q. Would you agree that opioids that plaintiffs' experts believe were clinically justifiable are less likely to cause overdose deaths?
MR. SOBOL: Objection.
A. I do not know the answer to that question, and again, this is a simulation about what might have been a clinically reasonable increase in opioid use.
It is not an assessment of whether, in fact, in these counties or in the

Page 724

nation as a whole these uses were present in the way that I simulate them.
BY MR. ROTH:
Q. And I think we did talk about this earlier during the course of the last two days, but you don't have any mechanism for translating your calculation of potentially justifiable MMEs in your thought analysis to either of your regression models?
A. Well, maybe I'm getting tired, but I'm not sure I understand that statement in the form of a question or question in the form of a statement. So how would I translate this to my regression model?
Q. Your regression models don't remove from the impact of defendants' promotion the clinically justifiable MMEs you calculate in your last opinion?
A. Again, I simulate them. I'm not identifying them as actually having occurred. And the purpose of my direct and indirect analysis is to quantify the impact of alleged misconduct, whether it resulted in a clinically justifiable use or otherwise.
Q. Okay. Did you review or rely

Page 725

on Dr. Kessler's report in this case?
A. I did not review or rely on it prior to filing my report.
Q. Do you know who Dr. Kessler is?
A. I do.
Q. Have you seen him testify in other cases you've been involved in?
A. I think he has testified in other cases I'm involved with. I want to say that one of the -- one of my old reports that you put in front of me somehow mentioned him.
But I certainly know who he is, and I believe he has testified in other cases I've been on, but I've not seen him testify.
Q. I'm trying to streamline simultaneously.
A. That's fine. Take your time.
Q. Do you agree with the statement that it is not a drug by itself that is regulated or that receives approval from the FDA; it is a drug for an intended use that is reviewed and approved by the FDA?
A. Well, again, as a layperson, not an FDA expert, I do understand that drugs are approved for specific uses.

Page 726

Q. All right. And we talked a little bit at the beginning of your deposition and a couple of other times about drug labels, so I just want to show you one for now.
A. Sure.
(Whereupon, Deposition Exhibit Rosenthal-28, Kadian Instructions for Use, was marked for identification.)
BY MR. ROTH:
Q. And refresh me. I think you said you did not review any -- I think that's wrong. I think you said you'd seen maybe the hydrocodone and OxyContin drug labels?
A. I specifically remember seeing those, reviewing those at some point during my analysis.
Q. But you did not do a comprehensive review of all the drug labels for all of the opioids at issue in this case?
MR. SOBOL: Objection, asked and answered.
A. I did not systemically analyze the drug labels.
///

Page 727

BY MR. ROTH:
Q. All right. I'm going to mark as Exhibit 28 the drug label for Kadian.
A. I really am going to have to get glasses.
Q. I apologize, these are printed so small.
Do you know what Kadian is?
A. I'm aware that it's in this case. I have -- I think I cite to some documents involving Kadian in my report.
Q. Do you know who marketed Kadian?
A. Well, it's probably not a great idea for me to guess. When I was reviewing some of those documents in preparation for my deposition, I did run across one, and I remember looking for the manufacturer. But I think it's Mallinckrodt, but I'm not a hundred percent sure.
Q. So if you look at the top of the first page, Kadian is a morphine sulfate extended-release capsule.
Do you see that?
A. Yes.

Page 728

Q. And there's a big black box on the left side of the front page.
Do you see that?
A. I see the black box.
Q. And in all capital letters at the top of the box it says: Warning: Addiction, abuse, and misuse; risk evaluation and mitigation strategy, REMS; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; interaction with alcohol; and risks from concomitant use with benzodiazapines or other CNS depressants.
Do you see that?
A. I see that.
Q. And that's in all capital letters.
A. It is.
Q. And then there are seven bullets in all bold that follow underneath in that same black box.
Do you see that?
A. I do.
Q. And have you read a black box warning like this one before?

Page 729

A. I have.
Q. In what context?
A. Well, when we were talking -- I'm -- I may have seen black box warnings in this case. When we were talking about this yesterday, I mentioned that black box warnings were a part of the factual base for the Zyprexa in other antipsychotic litigation I was involved in.
Q. Have you done, or are you aware of any research trying to ascertain whether marketing convinces doctors to ignore black box warnings such as the one in front of you?
MR. SOBOL: Objection.
A. As I mentioned yesterday, I am aware of research about black box warnings and the instances in which they have not been effective, and therefore, ignored by prescribing physicians.
And in the antipsychotic litigation I was involved in, I did some analysis that showed that while there was a short-run response to the black box warning, that prescribing returned to its original trend.

Page 730

BY MR. ROTH:
Q. Which antipsychotic drug were you involved in?
A. Well, you know about Zyprexa --
Q. Right.
A. -- from the case you put in front of me. I was an expert in several Risperdal cases as well, and the black box warning for atypical antipsychotics is common to all the second-generation drugs.
Q. Okay. If you look at the section is labeled Indications and Usage on the same page below the black box warning?
A. Yes.
Q. It says: Kadian is an opioid agonist indicated for the management of pain severe enough to require daily around-the-clock long-term opioid treatment, and for which alternative treatment options are inadequate.
Do you see that?
A. I do.
Q. And that's the FDA-approved indication and usage?
MR. SOBOL: Objection.

Page 731

A. Again, as I understand the FDA label, it contains information on the approved usage. I'm not -- neither a clinician nor an FDA expert. That is my layperson's understanding.
BY MR. ROTH:
Q. Okay. And do you have any reason to doubt that when the FDA approved the label for Kadian or any other opioid involved in this case, that it underwent the regulatory process required by federal regulations, including receiving studies of efficacy and safety?
MR. SOBOL: Objection, scope.
A. I could not say one way or another. I don't have the information to evaluate such a proposition.
BY MR. ROTH:
Q. Okay. Let's look at your report, paragraph 11, which was the summary of your opinions.
A. Yes. Not the table, just the paragraph?
Q. We can look at both.
A. Okay.

Page 732

Q. I think we've made it through all of them now.
A. Impressive.
Q. There may be one we didn't, so that's what I want to talk about.
A. Okay. Good.
Q. If you look back at paragraph 11, the second bullet in your summary says -- well, the first bullet, Promotion of pharmaceuticals increase their sales.
We talked about that I think a lot yesterday.
A. I think so.
Q. The second bullet. The alleged unlawful promotion of opioids, if proven, resulted in increased sales of opioids.
We talked about that some as well.
And then if you look at the table, I think those opinions are captured by Section VI of your report; is that right?
A. Section VI and VII generally go to the first bullet point, which is, you know, at a high level, promotion increases

Page 733

sales.
Q. I guess what I'm getting at is your econometric models are not cited as a basis for your opinions that either promotion increases sales or that the unlawful promotion, if proven, resulted in an increase in sales.
A. Yes. So the econometric models clearly show that the alleged unlawful promotion of opioids caused sales. I don't specifically cite to the econometric models there, but when I reach my conclusions from the models, we can go to that text, I do conclude that the model shows a causal relationship.
So even though I don't mention the econometric model specifically until I get to the next bullet point, the fact that I'm identifying the extent there is also premised on the existence of an effect.
Q. Okay. I understand now.
So if you look at the second bullet point, the last sentence says: As a result, I am of the opinion that the combined effect of the defendant manufacturers'

Page 734

promotion of prescription opioids since 1995 was a substantial contributing factor to the increase in the use of prescription opioids in the bellwether communities.

Did I read that correctly?

A. You did.

Q. And that is based largely on the econometric models?

A. It's based on all the foregoing.

Q. Okay. And I noticed the way you worded that sentence was that the promotion was a substantial contributing factor; is that right?

A. That's right.

Q. Not that the unlawful promotion was a substantial contributing factor, because as we've discussed, you have no opinion on whether defendants' promotion was unlawful or not; you're relying on counsel's assumption.

MR. SOBOL: Objection, asked and answered.

A. Again, I -- perhaps I should have repeated the unlawful promotion, if

Page 735

proven. So as you say, I demonstrate that promotion caused sales, and I assume that plaintiffs will prove that all promotion was unlawful.

MR. SOBOL: By the defendants.

A. All promotion by the defendants was unlawful.

BY MR. ROTH:

Q. And because you assumed that all promotion by the defendants was unlawful, that assumption would include promotion even if a sales representative only dropped off peer-reviewed literature at a doctor's office?

MR. SOBOL: Objection, asked and answered.

A. My analysis includes all promotion by defendants. When I calculate the but-for scenario, I remove that regardless if some of that promotion used materials that were FDA approved.

BY MR. ROTH:

Q. Your analysis also includes promotion by defendants even if the sales representative had no interaction with the

Page 736

prescriber?

MR. SOBOL: Objection, asked and answered.

A. I think what you're suggesting is that detailing may involve an interaction with someone else in the office? Is that what you're referring to?

And, yes, as I understand the matter at hand, that the entire promotional enterprise is what is at issue here, and so I have appropriately captured all detailing in my econometric model.

BY MR. ROTH:

Q. Your analysis includes all promotion by defendants even if that promotion did not result in any change in the prescriber's behavior after they were detailed?

A. Well --

MR. SOBOL: Objection.

A. -- actually, I would respectfully disagree with that. My analysis only attributes impact where promotion resulted in an increase in sales.

///

Page 737

BY MR. ROTH:

Q. But you include in your analysis details that may have had no effect on the particular prescriber's behavior?

MR. SOBOL: Objection, asked and answered.

A. And if that is the case, then it reduces the incremental effectiveness of promotion that I observe, and therefore, the calculated impact. The possibility that some details did not produce change is incorporated into the estimates.

BY MR. ROTH:

Q. You include in your analysis detailing where the prescriber's rate of prescription may have actually decreased after the detail?

MR. SOBOL: Objection, asked and answered.

A. My analysis will incorporate the effects, negative or positive. Obviously on average they're positive. If there are some negative changes after a detail for some reason, those again will reduce the measure of impact.

Page 738

BY MR. ROTH:
Q. You include in your analysis detailing even if the prescriber never prescribed the medicine he or she was detailed on?
MR. SOBOL: Objection.
A. Yes. Again, just like the -- any detailing that has no effect or a lower effect, I guess that would be a version of no effect, if the individual detailed never prescribed. And again, that will reduce the impact of detailing in my model.
BY MR. ROTH:
Q. You include in your analysis detailing to prescribers who were already the lead authors of journal articles on the addiction risk of opioids at the time they were detailed?
MR. SOBOL: Objection.
A. If there is such detailing in my data, again, my estimates will appropriately reflect a reduced effectiveness of promotion for those details.
BY MR. ROTH:
Q. Your analysis includes

Page 739

detailing to oncologists prescribing for end-of-life cancer pain?
A. Again, to the extent that my analysis does not grow the size -- sorry, to the extent that promotion does not grow the size of the market by expanding the use of opioids, detailing, for example, to oncologists who may already have been prescribing opioids will not result in impact.
Q. Your analysis includes detailing to prescribers who are hospice specialists for end-of-life pain.
A. To the extent that there is detailing to hospice providers in my data and those uses would have occurred regardless of the promotion, my analysis will appropriately capture those effects.
Q. Your analysis includes detailing to prescribers who may be performing surgery or trauma intervention in the emergency room?
A. Again, to the extent that those -- my analysis will calculate the uses that occurred in this market as a result of

Page 740

the alleged misconduct. Regardless of how those opioid prescriptions were used in practice, as I understand, is appropriate to my assignment.
Q. Stated differently, your analysis includes any detailing in the data regardless of to whom it was -- let me start over.
Stated differently, your analysis -- can we just get a clean question and answer. Say something.
A. Yes. What was the question? I don't know what the question is.
Q. Stated differently, your analysis includes any detail in the data, regardless of who was detailed, what was said or what behavior changed or did not after the detail?
A. So my analysis is consistent with my assignment in that I examine and quantify the aggregate market expansion that occurred as a result of defendants' promotion during the period from 1995 to the end of my data in 2018. I do not disentangle the types of detailing; however, to the extent there

Page 741

are differential effects of detailing across groups, those will be incorporated into the estimates.
MR. ROTH: Our time may be done. Let's take a quick break. And I may have more questions or someone else may.
THE WITNESS: Okay.
THE VIDEOGRAPHER: The time is 1:35 p.m. We're now off the record.
(Recess taken, 1:35 p.m. to 1:51 p.m.)
THE VIDEOGRAPHER: The time is 1:51 p.m. We're back on the record.
BY MR. ROTH:
Q. Professor Rosenthal, in Table 2 you calculate the total percent of MMEs attributable to defendants' promotion to be 44.9% of MMEs; is that right?
A. That's right.
Q. To what do we owe the other 55.1% of MMEs?
A. The other 55 -- excuse me -- .1 percent of MMEs are owed to the promotion that is not excluded in the but-for scenario,

Page 742

so again, because I start my data as early as I can in '93, there's a stock of promotion that builds up, and then there's non-defendant promotion. So all those things are left in the model.

Q. So it's promotion prior to '95 by anyone and non-defendant promotion thereafter?

A. That's correct.

Q. And that explains 55.1% of the MMEs with the remainder being explained by defendants' promotion from 1995 to 2018?

A. That's generally correct. You know, there's a constant in the model, which I think we could go to Table 1 and in Model B, so there's a baseline level of 2.4 million MMEs.

Q. Okay.

A. So that's in there as well.

Q. And then the same question for the indirect model, you calculate 67% of MMEs due to excess shipments, so is it fair to say based on your approach that the other 33% is due to the demographic and socioeconomic and other factors you model for?

Page 743

MR. SOBOL: Objection.

A. That would be due to the changes in all of those factors. Again, price actually has a negative effect, but the trend which is intended to proxy for non-defendant promotion and those other demographic, socioeconomic and healthcare variables.

BY MR. ROTH:

Q. Okay. And then if you look back at page 19 of your report, Figure 1.

A. Sorry, excuse me. I should just say again, in the indirect model as in the direct model there's also a baseline, right, so we're projecting growth from '95 forward. So there's a baseline level.

Q. Got it.

So if you look on Figure 1 on page 19, we haven't actually talked about this diagram yet.

A. Okay. Page 19. Yes.

Q. And is this a diagram you've used in other expert reports before?

A. I tailored this one specifically for this report, but I have used

Page 744

similar kinds of diagrams.

Q. And if we look at your diagram, you have the ecosystem of promotion in all of the lines between the various constituencies, and in the box in the middle, there's detailing, professional journals, samples, and meetings and events.

Do you see that?

A. Yes.

Q. And as we discussed, your model only accounts for detailing promotion, not for any of the other items in the box or any of the other boxes on Figure 1?

MR. SOBOL: Objection, mischaracterizes the testimony, asked and answered.

A. The direct model includes the measure of detailing only. The indirect model is intended to capture all of these kinds of marketing tools.

BY MR. ROTH:

Q. And then Table 3, which we've been round and around on, to the extent that you used Table 3 to assess the delta between a defendant's promotion percentage and the

Page 745

baseline percentage, that delta is capturing how that defendant's promotion relates to the aggregate average; is that right?

MR. SOBOL: Objection, asked and answered.

A. As we discussed earlier, I don't use the table in that way. I'm using it to narrow the aggregate by excluding individual defendants.

And when I do that, for example, to exclude Aventis, just as an alphabetically first choice, I am excluding ultimately the effect that I observe in the econometric model of Aventis' marketing, whether that generates sales for its product or someone else's product.

MR. ROTH: Okay. I think with that I am done for the time being. It's been a pleasure. I believe Mr. Metz has some questions, so I will be passing the microphone to him. And I can't promise I won't come back, depending on what else happens, but thank you so much.

THE WITNESS: Okay. Thank you.

Page 746

THE VIDEOGRAPHER: The time is 1:56 p.m. We're now off record.
(Recess taken, 1:56 p.m. to 1:58 p.m.)
THE VIDEOGRAPHER: The time is 1:58 p.m. We're back on the record.
EXAMINATION
BY MR. METZ:
Q. Good afternoon, Professor Rosenthal.
A. Good afternoon.
Q. My name is Carl Metz. I represent Cardinal Health, which is one of the distributor defendants in this case.
A. I apologize for forgetting the name of your employer as it were.
Q. That's all right. You're referring to testimony yesterday where you were asked about the distributor defendants, you named two companies, and the third name, Cardinal, eluded you. Yes?
A. Exactly, yes.
Q. Okay. At various places in your report, you refer to marketing defendants, correct?

Page 747

A. Yes, I do.
Q. And then in other places, and I'm sure this is not by design, you refer to the word "defendants" without differentiation.
MR. SOBOL: Objection to the form.
You can answer.
A. Yes, I believe I use that term. We could look to see how I use it.
BY MR. METZ:
Q. For example, in paragraph 64, which you're welcome to look at, and I'll quote this just partially. You say, quote: A causal relationship between the defendants', possessive, promotion and prescriptions of opioids.
Do you see that?
A. Yes.
Q. And do I understand based on your testimony over the last two days that despite using the singular term "defendants," we should not read that as referring to all defendants, correct?
MR. SOBOL: Objection.

Page 748

A. In this paragraph in particular, I'm talking about the defendants who have detailing that I'm measuring in my data, so those would be the marketing defendants.
BY MR. METZ:
Q. Okay. And by marketing defendants, you're not including any of the distributor defendants, correct?
A. I don't believe that they have marketing data in my data, so there may be places in my report where I refer to defendants where it's appropriate to talk about them more generally, for example, when I'm summarizing the complaint, but here I intend to describe the defendants who have detailing that is measured in the IQVIA data.
Q. Okay. So just to be clear, not -- as you believe it, not -- that does not include the distributor defendants, correct?
MR. SOBOL: Objection, asked and answered.
A. I believe that is true.
///

Page 749

BY MR. METZ:
Q. Okay. And it also does not include the pharmacy defendants, correct?
MR. SOBOL: Objection, asked and answered.
A. Yes, that is correct.
BY MR. METZ:
Q. So we take another example, paragraph 78, where you say, quote: An alternative method of identifying the impact of the defendants', possessive, misconduct, is to use an indirect method.
Do you see that?
A. Yes.
Q. And there again, you're using the term "defendants," but how we should understand that is the marketing defendants, correct?
A. Well, the -- in -- excuse me, the indirect approach -- it is getting to be late -- is, as you know, a residual approach, so it inherently is looking at all of these demographic, socioeconomic and healthcare factors that could have driven higher opioid use and attributes that which is left to the

Page 750

misconduct.
I think it's a little bit less clear about how that analysis might be used to assess liability for distributors. I have not been asked to do that, but the indirect analysis, because it's not measuring the conduct of a specific group, could be open to a broader interpretation.
Q. Have you disclosed any opinions that, based upon your indirect model, you draw conclusions about distributor defendants' conduct?
A. I have not. I have not drawn those conclusions.
Q. And you mentioned the detailing data, but just to be clear, you did not include in your direct model any data series that you understood were measuring the conduct of the distributor defendants; is that correct?
MR. SOBOL: Objection, asked and answered.
A. I have not measured the conduct of the distributors or included that in my model.

Page 751

BY MR. METZ:
Q. And the same would be true of the pharmacy defendants, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not measured the conduct of the pharmacies and included that in my models.
MR. METZ: Just so it's not recurring, I'm five questions in. What have I asked and answered? Or what have I asked previously?
MR. SOBOL: All of this was covered by Mr. Roth this morning and yesterday.
MR. METZ: Okay. I disagree.
BY MR. METZ:
Q. You testified at several points that the design of your model is intended to capture an aggregate effect on MMEs sold, correct?
A. That's correct.
Q. And in part what that means is you've not reported your results in a way that allows you to identify any particular

Page 752

set of prescriptions that combine to make up the additional MMEs you've identified in your analysis, correct?
A. The way my analysis works is to analyze the actual data and identify a quantity of prescriptions in aggregate that would not have been filled absent the promotional misconduct.
As I noted yesterday, because the but-for scenario did not occur, we cannot explicitly observe which individual prescriptions would not have been filled. So there's a conceptual impossibility to the statement that you're describing.
Q. Okay. So just to be clear, your answer is yes, but for the reason that it would be impossible?
MR. SOBOL: Objection, asked and answered.
A. Yes, and my analysis -- as you know, my assignment was to estimate the impact of the alleged misconduct and to quantify that in aggregate.
BY MR. METZ:
Q. I understand. The alleged

Page 753

marketing misconduct, correct?
A. The alleged marketing misconduct.
Q. And am I correct that the data that you use in your calculation does not contain identifying information for individual prescriptions, correct?
A. My data do not contain individual prescription identifiers. I assume by that you mean something like a member identifier.
Q. Anything that would enable you to identify a specific prescription that's within the sum of your conclusions?
A. No. Again, because of -- for privacy reasons, my data are deidentified.
Q. Okay. Now, you testified yesterday that you have not formed any opinions about the separate role of doctors in causing an increase in the MMEs that you measured.
Do you recall that testimony?
A. I believe I described the fact that of course doctors are in the causal chain, they're the ones writing the

Page 754

prescriptions.
Q. Right. You testified that the conduct you're attempting to measure flows through doctors, but you're not forming a separate opinion about their independent role in the causal chain, what influence they exerted in the causal chain, correct?
MR. SOBOL: Objection.
A. I have not separately examined, I guess, doctor behavior. Again, because it's tautologically true that every prescription is written by a physician, I struggle with that concept.
BY MR. METZ:
Q. I understand.
Now, you also testified yesterday that you've not formed any opinions about whether any quantity of the increase in MMEs identified in your opinions was medically necessary or unnecessary, correct?
MR. SOBOL: Objection. On the direct model, you mean?
BY MR. METZ:
Q. On the direct model, do you recall that testimony?

Page 755

A. Yes. In the direct and indirect models, I do not differentiate between medically necessary and unnecessary prescriptions.
Q. Okay. And in part what that means is you have not endeavored to identify any subset of your total measured MME increase that consists of prescriptions that do not meet an appropriate standard of medical care; is that correct?
MR. SOBOL: Objection, asked and answered.
A. I have not evaluated the -- nor am I a clinical expert, just to be clear -- the medical necessity of any of the prescriptions that I find were caused by the alleged misconduct.
BY MR. METZ:
Q. Right. You've not done that at the level of individual prescriptions in the first instance, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not done analysis at the level of individual prescriptions at all.

Page 756

BY MR. METZ:
Q. Okay. And you've not done that for an aggregate sum of prescriptions either, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not evaluated medical necessity of any prescriptions.
BY MR. METZ:
Q. All right. Am I correct that you've also not undertaken to identify any subset of your total MME increase that consists of prescriptions a pharmacist should have refused to fill for whatever reason after it was presented by a patient?
MR. SOBOL: Objection.
A. I have not been asked to examine the decisions of pharmacists or the conduct of pharmacists as it relates to this matter.
BY MR. METZ:
Q. Okay. So you've not done that for the reason you just stated?
MR. SOBOL: Objection, asked and answered.

Page 757

A. I have not examined the conduct of pharmacists.
BY MR. METZ:
Q. Okay. And you're not an expert in what constitutes responsible conduct of pharmacists, correct?
A. I'm not an expert in what constitutes responsible conduct for pharmacists.
Q. Based on your role as a healthcare economist, are you, though, generally aware that pharmacists have certain obligations relating to the dispensing of pharmaceuticals?
A. I am aware generally where pharmacists fit in the supply chain. I am not familiar with the specifics of their professional guidelines.
Q. Okay. And recognizing that you've already told me you do not have the expertise to do this, it was not your assignment, and you do not have the visibility at the prescription level -- I just want to confirm for the record -- you have not evaluated whether individual

Page 758

prescriptions that are somehow within your total MME calculation were properly filled from the perspective of a pharmacist?
MR. SOBOL: Objection.
Objection, asked and answered.
A. I have not evaluated -- I guess it sounds to me like you're just saying that there's a notion of medical necessity that applies to pharmacists, but I have not evaluated the medical circumstances around a particular prescription, whether it pertains to the doctor's decisions or the pharmacist's decisions.
BY MR. METZ:
Q. Thank you for that. And just to be clear, because that's not what I was, in fact, suggesting, I'm just trying to confirm what is not done within the contours of your opinions, not necessarily the reasons for them or suggesting that you should have done these things.
MR. SOBOL: Well, she's going to give complete answers to the questions.
MR. METZ: I don't mind her

Page 759

giving complete answers.
MR. SOBOL: Okay.
BY MR. METZ:
Q. You similarly have not -- it follows, I think, by not having done that analysis at the level of individual prescriptions, you've also not evaluated whether individual pharmacists improperly dispensed in response to prescriptions they were presented with, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not evaluated the conduct of individual pharmacists in my analysis.
BY MR. METZ:
Q. Okay. And you've not undertaken such an evaluation at the level of pharmacies as a whole, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not evaluated the contribution of pharmacies to these prescriptions.
///

Page 760

BY MR. METZ:
Q. And you've not evaluated that at the level of chains of pharmacies, correct?
MR. SOBOL: Objection, asked and answered.
A. I have not evaluated the conduct of pharmaceutical chains or pharmacy chains to the opioid prescriptions.
BY MR. METZ:
Q. Now, in Table 2 of your report, you disclose some information on a percentage basis under a heading that it is the percent of MMEs attributable to challenged promotion, correct?
A. I think that's right. I'm sorry, just let me get the table. Percent of MMEs attributable to challenged promotion, yes.
Q. Okay. Now, would I be correct in surmising that for all the reasons we've been discussing, it would not be correct to characterize the results reflected in Table 2 as reflecting a percentage of MMEs prescribed in excess of legitimate medical need?

Page 761

MR. SOBOL: Objection, asked and answered.
A. It is -- I do not describe my calculations that way, and as we discussed earlier, I have not evaluated the medical necessity of any prescriptions.
BY MR. METZ:
Q. Okay. My question was close to that, but it's not that.
They're not described that way, and it would be incorrect to describe them that way based on the analysis you conducted, correct?
MR. SOBOL: Objection, form, asked and answered.
A. I did not analyze medical necessity. My results do not pertain to medical necessity and, like anything, they are not, it would be incorrect to label them medical necessity or anything else that they are not.
BY MR. METZ:
Q. Thank you.
You would also agree with me that again, for the same reasons we've been

Page 762

discussing, it would not be correct to characterize Table 2 as reflecting a percent of MMEs dispensed by pharmacies or pharmacists in excess of legitimate prescriptions?

MR. SOBOL: Objection, asked and answered.

A. I am not sure whether -- because I have not analyzed the conduct of pharmacists or pharmacies -- whether another expert might deem these same units that I calculate are caused by promotion to have been in excess from the point of view of the conduct of pharmacists or pharmacies.

I have not done that analysis. So you're asking me a question about how these -- these analyses might be used by others, as far as I'm concerned.

BY MR. METZ:

Q. I'm asking the author of the analysis the proper interpretation of the analysis, and as the author of the analysis, it would not be a proper interpretation that what this reflects is a quantity of opioid pharmaceuticals dispensed in excess of

Page 763

legitimate prescriptions, correct?

MR. SOBOL: Objection, asked and answered, mischaracterizes prior testimony.

A. When you use the word "legitimate," to me that sounds like it -- I mean, literally it's a legal term, and so what I've calculated here, which I have labeled absolutely clearly, is the percent of MMEs attributable to allegedly unlawful -- I say challenged -- unlawful promotion.

So that is illegitimate in a sense, in the sense that I understand plaintiffs' counsel intend to prove that the defendants' promotion from 1995 through 2018 was unlawful.

BY MR. METZ:

Q. Okay. Let me ask it in a different way.

The information compiled in Table 2 could not be correctly characterized as having been compiled so that it would show an amount of opioid prescriptions that were dispensed based on prescriptions a pharmacist should have refused?

Page 764

MR. SOBOL: Objection.

BY MR. METZ:

Q. That's not the basis on which Table 2 is compiled, correct, as its author?

MR. SOBOL: Objection, asked and answered several times now.

A. I have not in my analysis analyzed the behavior of pharmacies or pharmacists, and so I cannot describe these data as reflecting the behavior of pharmacies or pharmacists.

Because of this issue around the causal chain that pharmacies, in fact, dispense prescriptions, I don't know if someone else would attribute this -- these same excess units to pharmacies. I haven't done that analysis.

I am not attributing these to pharmacists' behavior, but they are in the causal chain. So I'm saying I have described these as those units that are caused by the allegedly unlawful promotion. That's what they are.

Whether or not the pharmacists' or pharmacies' conduct is fully overlapping

Page 765

with the marketing manufacturers here, I don't know. I haven't been asked to look at that question.

BY MR. METZ:

Q. In running the analyses that resulted in the numbers in Table 2, it was never at any point your intention to compile a table from which one would interpret that as a volume of opioid prescriptions that were dispensed in excess of legitimate -- prescriptions that a pharmacist should have fulfilled after being presented with such prescriptions.

MR. SOBOL: Objection, asked and answered, mischaracterizes prior testimony.

BY MR. METZ:

Q. Isn't that correct?

MR. SOBOL: Well, objection. Answer -- asked and answered, mischaracterizes prior testimony.

If you want to give the same answer or whatever, go ahead.

A. I'm not sure. In my analysis, I did not consider whether a pharmacist or

Page 766

pharmacy should have done one thing or another. Again, they're in the causal chain. They must have been involved in filling these prescriptions, but I have not separately analyzed the conduct of those pharmacists or pharmacies; and moreover, when you use the word "should," that sounds like there's either a professional judgment or a legal judgment, and I have not analyzed that kind of judgment.

BY MR. METZ:

Q. Okay. I think I asked a complicated question, more so than I intended to be. Mine is just very simple.

As the person who compiled the information in that table, it was not done for the purpose of making the sort of claim that I just -- just stated in my previous question, correct? That was not the purpose of compiling the information in that table.

MR. SOBOL: Objection, asked and answered.

A. The purpose of Table 2 was to fulfill the part of my assignment where I was asked to quantify the impact of allegedly

Page 767

unlawful promotion on MMEs. That was the purpose of Table 2.

BY MR. METZ:

Q. Okay. Now, you testified this morning that you've not conducted any analyses relating to suspicious order monitoring for any defendant.

Do you recall that?

MR. SOBOL: Objection, asked and answered.

A. Yes.

BY MR. METZ:

Q. To take that one step further, you conducted no analysis seeking to identify any subset of your total MMEs increase that consists of opioid medications that were part of any order that plaintiffs or their experts have alleged to be suspicious. You've not conducted that analysis, correct?

A. I have not conducted an analysis of suspicious orders in -- within the context of my analysis and any suspicious order analysis.

Q. And as we discussed a few minutes ago, because your results are based

Page 768

on aggregate data for total MMEs, they do not contain the identifying information that would allow you to trace them back to individual prescriptions, correct?

MR. SOBOL: Objection, asked and answered.

A. The data I have from the National Prescription Audit do not have identifiers, so in these data, I cannot trace them back to individuals.

BY MR. METZ:

Q. Okay. And therefore, those MMEs are also not traceable back to individual pharmacies, correct?

MR. SOBOL: Objection, asked and answered.

A. Again, in the aggregate data I have, that is correct.

BY MR. METZ:

Q. And you've not attempted to trace them, correct?

MR. SOBOL: Objection, asked and answered.

A. I would have to get a different dataset for that.

Page 769

BY MR. METZ:

Q. Okay. And therefore, those MMEs are also not traceable back to individual orders that pharmacies placed with their wholesale distributors, correct?

MR. SOBOL: Objection, asked and answered.

A. My data are not at the right level of disaggregation to track orders to or from pharmacies.

BY MR. METZ:

Q. And for that reason or other reasons, you've not attempted to make any such linkage, correct?

MR. SOBOL: Objection, asked and answered.

A. I have not been asked to make any such linkage, and so, therefore, I have not acquired the data or undertaken that assignment.

BY MR. METZ:

Q. And for that reason, if not others, would you agree with me that it would not be correct to characterize Table 2 as reflecting a percentage of MMEs distributed

Page 770

as a result of suspicious orders?
MR. SOBOL: Objection.
A. These are -- oh, as a result of suspicious orders, sorry. It is -- these are a percentage of MMEs that were distributed as it were. They reached patients at a pharmacy as a result of promotional misconduct. I have not analyzed suspicious orders. I do not know how those two things would intersect. These percentages reflect promotional impact.
MR. METZ: Thank you. Whoever is on the phone, if you would hit mute, please. We're hearing some background. Thank you.
BY MR. METZ:
Q. Would you agree with me that as a general proposition, in a regression analysis, causality cannot be inferred by data analysis alone, rather, one must infer that the causal relationship exists on the basis of an underlying causal theory that explains the relationship between the two variables?
A. It sounds like you're reading

Page 771

from a textbook. Generally, causation begins with an economic theory. I would agree with the general premise of that statement.
Q. And would you also agree that as a general proposition in regression analysis, even when an appropriate theory has been identified, causality can never be inferred directly; one must also look for empirical evidence that there is a causal relationship?
MR. SOBOL: Objection, asked and answered.
A. I would agree that in general, economists use both theory and empirical evidence to make causal inferences, yes.
BY MR. METZ:
Q. And consistent with those principles for your work in this matter, you have not posited a causal theory of how your calculation of the increase in total MMEs might be causally related to any alleged suspicious order by distributor defendants, correct?
A. I have not posited a theory related to suspicious orders. I have not

Page 772

been asked to examine that question in any way in my analysis.
Q. And it follows you've also not looked for empirical evidence of any such causal relationship, correct?
MR. SOBOL: Objection, asked and answered.
A. Yes, I have not -- I have not undertaken an analysis of suspicious orders.
BY MR. METZ:
Q. Okay. New topic.
In paragraph 56 of your report, you -- and I'm reading a truncated version of the quote, but, quote: While documents produced in discovery show many --
MR. SOBOL: Wait one second, please, if it's going to be truncated.
MR. METZ: Please.
A. 56? Yeah.
MR. SOBOL: Where are you?
THE WITNESS: At the bottom of page 38?
MR. METZ: I believe so.
THE WITNESS: Yes.
///

Page 773

BY MR. METZ:
Q. You state: While documents produced in discovery show many examples of such promotional efforts beyond detailing, for the purposes of my econometric analysis, I rely on detailing contacts to measure promotion for several reasons.
Do you see that?
A. I do.
Q. Okay. Now, you testified about this yesterday, but I have a few follow-up questions.
A. Sure.
Q. As I understand your testimony and your report, one reason you rely upon detailing is that it's a form of marketing for which you have enough data to enable you to perform a time series regression; is that correct?
MR. SOBOL: Objection.
A. That is one of the reasons that I state in this paragraph, in addition and first and foremost, to it being a very important form of marketing, if not the dominant form of marketing.

Page 774

BY MR. METZ:
Q. Okay. So some of the other forms of marketing are not systematically tracked in data in the same way that the detailing is, correct?
A. Yes, that's correct.
Q. And you also believe, do you not, that -- this is a quote: From an econometric standpoint, detailing is a good proxy for total promotional effort, including -- and closed quote -- including those other forms of marketing for which there's not systematic data, correct?
A. Yes, that's correct.
Q. All right. Now, in the following paragraph, paragraph 57, and then in Figure 5, you identify a series of what are labeled key events that would have affected the receptiveness of prescribers and patients to promotional messages about the safety and effectiveness of opioids.
Do you see that?
A. I do.
Q. Okay. And your understanding is plaintiffs allege that manufacturer

Page 775

defendants were responsible for those key events?
A. As you can see, looking at Figure 5, the events in red include many policy/regulatory events, so the events in green are ones that are described in Dr. Perri's report, among other places.
Q. Okay. So the answer to my question would be yes, for the green-flagged key events?
A. Yes.
Q. How did you --
MR. SOBOL: Or the answer she gave.
BY MR. METZ:
Q. How did you identify this list of key events?
A. The list comes from -- there's an FDA timeline that's available on their website that is included in my documents relied upon; the complaint, Dr. Perri's report. It's an aggregation of all those places.
Q. Okay. Did you include every event that's listed in those sources?

Page 776

A. No, I did not.
Q. With reference to the events flagged in green, what were your criteria for inclusion from among the various events that were candidates based on those sources?
A. Sure. Again, as I said earlier yesterday, I believe, I sought to describe some of the key events that were going on at different stages of the analysis during the time frame, so I was looking to identify events over time.
In some cases there might be other events that coincide with these same events. I focused in terms of the events in green in particular ones that are highlighted in the complaint and in Dr. Perri's report.
Q. Now, in your testimony yesterday, you were asked about one of these events. It was the consensus statement of the American Academy of Pain Management and the American Pain Society.
A. Yes.
Q. Do you recall that?
A. I do.
Q. And I want to ask a little

Page 777

follow-up about your testimony which, based on the rough transcript, was in part that that consensus statement related to the undertreatment of pain and the need for more attention to the treatment of pain and the effective use of opioids for such treatment.
Do you recall that?
A. Yes, that was my summary of it.
Q. And why would that make that event significant?
A. I don't know what you mean by why would that summary make it significant. Again, it's an event that's talked about in Dr. Perri's report and talked about in the complaint.
Q. This is a -- this is an event that, based on the information referred to in those places, you were hypothesizing could have had a causal relationship with the sales of MMEs, correct?
A. That's right. I understand that Dr. Perri's opinion and plaintiffs intend to prove that these kinds of professional society recommendations were manipulated by defendants.

Page 778

Q. Okay. And one of the reasons why that statement as you described it yesterday would be hypothesized to have a causal influence is it referred to the notion that there's an undertreatment of pain, correct?
A. Yes.
Q. And another of the reasons was because it referred to the notion that opioids could be effective treatment for such pain, correct?
A. That's correct.
Q. Does the reputation of these two bodies play a role in its being considered a key event?
A. Again, for my purposes, it's a notable event because it is featured in Dr. Perri's analysis and others, and I'm using Figure 5 to talk about particularly the nonmarketing mechanisms that were allegedly part of the overall effort to grow the market for opioids.
So the reputation of the professional societies is likely a reason for which the marketing defendants allegedly

Page 779

influenced those -- that consensus statement and those guidelines because that is an effective way of delivering their message.
Q. Now, looking again at Figure 5, I see you have it in front of you, another of the key events that's flagged reads capital V, cap A, "Pain as 5th Vital Sign."
Do you see that?
A. I do.
Q. Do you have an understanding of what that's referring to?
A. It was a VA statement, again, around the need to more closely monitor and treat pain.
Q. And the VA that you're referencing there is the U.S. Department of Veteran Affairs?
A. It is.
Q. And why would that be significant?
A. Again, this is something that is described in Dr. Perri's report and is another example of the way defendants' message was legitimized through the activities of other stakeholder groups,

Page 780

including the VA.
Q. Okay. And as you say "defendants" in that testimony, you mean marketing defendants?
A. Yes, marketing defendants.
Q. Do you recall anything else about the VA's message other than it was around a need to more closely monitor and treat pain?
A. I don't recall all the details of it. I believe it's cited in my documents, so we could pull it up.
Q. Okay. But it is, as you recall it, thematically consistent with the previous document in that it identified a need to have more expansive treatment of pain and identified opioids as one way of doing that?
A. Yes. And I think what it became known for was this notion of the fifth vital sign.
Q. That pain is the fifth vital sign?
A. That's correct.
Q. Okay. And again, in the language we were referring to a few minutes

Page 781

before, you had a causal theory that a publication like that by an organization like the VA could have been causally related to the sale of opioids, correct?
A. Yes. I believe that's what I describe in my report, that all of these events collectively created an environment in which physicians were more receptive to pharmaceutical marketing.
Q. And because it's flagged in green, the causal theory is that it would be positively correlated with sales, correct?
A. That was my causal theory, yes.
Q. And so can we look at Table 1 in your report, which is the --
A. Regression results.
Q. Well, it's the output from your direct regression.
A. Yes.
MR. SOBOL: Do you have a page?
MR. METZ: I do.
THE WITNESS: 47.
MR. SOBOL: Thank you.
BY MR. METZ:
Q. And you testified about this

Page 782

yesterday and over the course of today, and I'm just going to reference a couple of things to orient us and then I have some follow-up questions.

In your Model B, as you've testified, you do not include a variable for marketing conduct other than -- other than detailing; isn't that correct?

A. The variable that I included in my model is detailing, the stock of detailing, yes.

Q. Okay. And your findings based on that model purport to explain more than 99% of the variation in total MMEs, correct?

A. Based on this model, which also includes the price index, yes.

Q. Okay. And that 99% is based on the R-squared statistic, correct?

A. Yes.

Q. And then in your Model C, you include five additional dummy variables to test for whether specific events from your Figure 5 are having an influence on total MMEs, correct?

A. That's correct.

Page 783

Q. And you talk about that a little in paragraph 73 of your report?

A. Yes.

Q. And in -- as you disclose there, in your -- and as reflected, I think, in Table 1, when you ran the model, including those five dummy variables, you found that two of them were statistically significant at the 5% level, correct?

A. That's correct.

Q. One is what you've titled the 1999 Federation of State Medical Boards Model Guidelines dummy variable, correct?

A. Yes.

Q. And the other is the rescheduling of hydrocodone, correct?

A. That's correct.

Q. Now, you've assigned names to these dummy variables, but wouldn't you agree that by definition, a dummy variable is not actually testing for the influence of the specific event described in its name?

MR. SOBOL: Objection.

A. Well, I'm not sure I would agree with that. They're intended to capture

Page 784

an event based on their timing. They are not -- they don't reflect a quantum, other than existence, and so hence, the name dummy variable.

BY MR. METZ:

Q. Okay.

A. But they are still intended to capture some kind of timing.

Q. They're intended to capture the -- an effect that's occurring with that time and an effect that may be correlated with the variable of interest, correct?

A. Yes, an effect on the variable of interest.

Q. Okay. And so it's in contrast with, for example, your detailing data, which is populated by data that changes month to month. A dummy variable, especially as you've used it, has two settings, correct?

A. A dummy variable, as anyone would use it, as it's defined, is either a one or a zero. They're very commonly used in regression analysis, as you may know.

Q. I know.

And so -- and you described

Page 785

this in paragraph 73. In your model you have a series of months where the dummy variable's value or the value of the data associated with it is zero, correct?

A. That's correct.

Q. And at a point in time that you determine for purposes of trying to capture the effects of some event of interest, you changed that value from zero to one, correct?

A. That's correct.

Q. And in your model you leave it turned on as it were --

A. Yes.

Q. -- from then to the end of your data series, correct?

A. True.

Q. And that's not an automatic design feature one could turn a dummy variable on and off, correct?

A. You can do whatever you like, of course, but for the most part, when we think about something that is released, that it's on and that it stays on. Unless, for example, there was a policy that was then reversed and then it would make sense to turn

Page 786

it off.
Q. Right. So I understand that you selected the timing of these dummy variables based on their proximity to the events after which they're named, correct?
A. Yes.
Q. But to be precise, regardless of the names, what they're capturing are changes in the dependent variable, which in this case are the total MMEs, that are correlated with influences existing at the time the dummy variable is turned on, correct?
MR. SOBOL: Objection, form.
A. Yes, they are capturing any shift that occurred around that time.
BY MR. METZ:
Q. And if there are multiple events around that same time that are correlated with the explanatory variable in a similar way, the dummy variable will pick up their collective influence, correct?
A. Yes. I believe I said the same thing when I explained why ultimately I do not use Model C.

Page 787

Q. And you originally created Model C as a robustness test, correct?
A. It is a check on Model B to see, well, we had these events, if we picked the ones that we think are important, do we see any shift around that time period.
So it's a check in that sense, and it seems to me based on the results that it's not a sensible direction to go.
Q. Well, maybe my question is meant to be -- I meant it to be a little bit simpler.
You designed Model C as a test of the robustness of Model B, rather than running that as a fully formed model. Isn't that what you say in your report?
MR. SOBOL: Objection, asked and answered.
A. I describe it in that way as well, and in doing so, I look at Model C on its own merits as well.
BY MR. METZ:
Q. Okay. And the purpose -- so leaving aside your valuation of the merits of Model C on its own, I want to focus on the

Page 788

robustness test purpose.
The purpose of a robustness test is to see the extent to which the results of a regression model are sensitive to changes in the underlying assumptions of that model; is that correct?
A. Yes.
Q. And you agree that robustness is important to the validity of a regression model and its interpreted results?
MR. SOBOL: Objection, form.
A. It's one way that we look at the validity of the model.
BY MR. METZ:
Q. And so specifically here, to the extent your purpose was a robustness test, you were testing the assumption -- and I'm quoting again from paragraph 73 -- the validity of the assumption that, quote, Model B implicitly accounts for non-detailing events and policies, closed quote, correct?
A. Yes.
Q. And you tested that by examining whether indicators of specific events and policies should be explicitly

Page 789

included in the model, correct?
A. Yes.
Q. Now, when you originally disclosed your report, you concluded that jointly all five events are not statistically different from zero, correct?
MR. SOBOL: Objection.
A. Yes, that was -- it was -- the wrong test was referenced when the write-up was, although the right test was included in the results, but I was looking at the wrong test when I summarized that.
BY MR. METZ:
Q. Okay. And so just to hone in on the particular language that's used in your report, when you say jointly, all five events are not statistically different from zero, based on the discussion we had a minute ago, you mean the five dummy variables named after events as listed in Table 1 were not statistically different from zero as stated in your report originally?
MR. SOBOL: Objection. Well, you want her to testify on the basis before the errata?

Page 790

MR. METZ: I'd like her to answer my question. But she's doing a fine job. If you don't understand my question, I'm happy to clarify.

A. No, I think you just said something that would be -- I understand is accessible, but it would be a strange way to describe the results.

So I say that the dummies are or aren't significant, so I'm inferring from the dummy variables what I can learn about modeling those events in that on/off way.

BY MR. METZ:

Q. Well, if I -- if we took the sentence that's in your report that I quoted, the one beginning "jointly," and replaced the word "events" with "dummies," would it cease to be accurate?

A. It would not. I'm just saying it would not be unusual for someone to describe their statistical results using dummy variables based on what the dummy variables are intended to represent.

Q. Okay. And one of the reasons you've given for rejecting Model C was you

Page 791

found a counterintuitive result for your hydrocodone event, correct?

MR. SOBOL: Objection.

A. I gave that reason in addition to the fact that it does not fundamentally change my results.

BY MR. METZ:

Q. Okay. But that was one of your reasons?

A. That's correct.

Q. And because it's a dummy variable, that result may not be counterintuitive. It may be capturing an effect other than hydrocodone, correct?

MR. SOBOL: Objection.

A. Again, it's counterintuitive based on the event I put the dummy variable in to model, and like you, I wonder if it's capturing something else.

BY MR. METZ:

Q. Okay. It would be contrary to your expectations for why you put a dummy there in the first place and why you named it the way you did. But that doesn't rule out that it's accurately measuring some event

Page 792

that's actually going on at that place, just not one that you had hypothesized?

MR. SOBOL: Objection, form, asked and answered.

A. Yes, it is possible that it is appropriately capturing something.

BY MR. METZ:

Q. Okay. And that was one of two events that you found that individually was statistically significant at the 5% level, correct?

A. That's correct.

Q. And you also, as you now disclosed in your errata, you also found that jointly, all five events are statistically different from zero, correct?

A. That's correct.

Q. Okay. And returning to the robustness test purpose of creating Model C in the first place, that shows, does it not, that your Model B is sensitive to some events outside the construct of Model B that are being captured by those dummy variables?

MR. SOBOL: Objection.

A. I would disagree. If you

Page 793

look -- if we go to look at the charts and you look at the extent to which my predictions changed, they hardly change at all. The coefficients on the variables of interest, they hardly change at all.

BY MR. METZ:

Q. Well --

A. The results are virtually the same.

Q. Your coefficient for -- you have three time period coefficients for the detailing variable, correct?

A. That's correct.

Q. And as you've discussed, you also construct the detailing variable differently in the different periods, correct?

A. We discussed that. We can go over it again, but yes.

Q. I'm just referencing that.

A. Yes, let's reference that.

Q. All right. The first time period detailing variable changes from Model B to Model C, does it not?

A. It changes a small bit, but

Page 794

again, if you look at the predictions of actual versus but-for, the differences are minute.
Q. I'll get to that in a second.
It changes, yes?
MR. SOBOL: Well, no, objection. She answered the question.
MR. METZ: Fair enough.
THE WITNESS: In my opinion --
BY MR. METZ:
Q. I'll ask a different question.
A. Okay.
Q. Specifically, it changed by reporting a lower value in Model C for that coefficient as compared to Model B.
MR. SOBOL: Objection, asked and answered.
A. The coefficient is lower, yes.
BY MR. METZ:
Q. And the interpretation of that is that in that Model C, when you include these dummy variables, some amount of the -- what had previously been reported as the influence of the detailing is now being no longer reported as the influence of the

Page 795

detailing, and it is being ascribed to one or more of the dummy variables. Yes?
MR. SOBOL: Objection.
A. There is some quantum. It is a very small difference. In my view, given the limitations of Model C and given the fact the results are different by such a small amount, Model B is preferred.
BY MR. METZ:
Q. Okay. And you have a second period in which you report the detailing variable, and the coefficient on that variable also changes from Model B to Model C, correct?
A. Yes, they do. The point estimates are different.
Q. Okay. And they change in the same direction in that, again, the detailing is credited with less of an influence, and --
A. I'd actually have to look.
Q. -- some of that influence is credited instead to the dummy variables, correct?
A. There's -- you're right. There is a small decrease in the second coefficient

Page 796

and the third coefficient is the same.
Q. Now, you've said many times that it is a small decrease, but a couple of follow-ups about that.
Is it standard practice in econometrics to actually make qualitative judgments about the differences between coefficients based solely on their numeric values?
MR. SOBOL: Objection.
A. I do not include a conclusion about the quantitative difference between these coefficients. I explain my reasons for selecting Model B, and we've talked about them. In terms of the results of Model C, not based on the magnitude of that difference.
Had there been a larger magnitude of difference, I might have considered the challenges with Model C differently.
BY MR. METZ:
Q. I'm asking a simpler question, which is: To an econometrician, do the -- what I'll call the real numbers -- so not

Page 797

their weighted or contextualized or -- versions, but just the pure number, comparing coefficients, coefficient A to coefficient B, based solely on the number associated with them, is that a comparison that econometricians would typically make when evaluating the significance of a change?
MR. SOBOL: Objection, asked and answered, form.
A. I -- economists, econometricians, almost always make qualitative judgments about models because of course there's part of it that is based on theory as we've described.
So might an econometrician make a quantitative analysis? Maybe. She might also make qualitative judgments about which model is preferred. Not everything can be described quantitatively.
If I wanted to know exactly how different these models are, I could make that quantitative comparison. I was not attempting to do that here.
BY MR. METZ:
Q. I'm just referring back to

Page 798

where in response to my questions you kept saying the difference was small.
And so as further explanation on that, in comparing coefficients, don't you also need to know the scale against which they're being measured?
MR. SOBOL: Objection, asked and answered.
BY MR. METZ:
Q. If you're comparing just the real numbers, you need to know the scale to which those correspond, correct?
MR. SOBOL: Objection, asked and answered, mischaracterizes prior testimony.
A. Yes, and the scale is evident here, and again, if we go to the predicted values, the scale is evident there as well.
BY MR. METZ:
Q. Did you not testify repeatedly yesterday that the reason it doesn't matter that you have an inflationary depreciation rate is because all that that does is it gets caught up in muting the impact of the coefficients on the particular variables at

Page 799

the particular times that they're measured?
MR. SOBOL: Objection, asked and answered.
BY MR. METZ:
Q. Didn't you testify to that?
MR. SOBOL: Objection, form, asked and answered.
A. I don't believe that I stated that in the way that you have. All I said is that the fact that promotional stock inflates doesn't necessarily mean that the effect has to inflate in the same way because the measured promotional effectiveness, as we see in both of these models, I find it decreasing over time, and that counteracts.
I didn't say it doesn't -- it doesn't have any effect. I'm just saying that the effect of the misconduct is a function both of the magnitude of the stock and of the promotional effectiveness.
BY MR. METZ:
Q. And also in reference to your answers to me that these changes don't matter because the effect was small, it's also the case that those changes, as you characterized

Page 800

as small, are the result of five dummy variables you included as a singular robustness test, not a comprehensively designed model attempting to comprehensively control for these kinds of external events, correct?
MR. SOBOL: Objection, form, asked and answered, mischaracterizes prior testimony.
A. As I described yesterday, and I would restate now, given the performance of these selected dummy variables, given the adjusted R-squared of the model, the notion that adding all of the events would improve the performance of the model makes little sense to me. And that is why I did not run a model with every dummy variable in it.
BY MR. METZ:
Q. Well, after running a model with dummy variables, two of which individually were statistically significant, and the five of which were collectively statistically significant, you did not attempt to construct a further model with more dummy variables to see whether or not

Page 801

that had a greater impact on your measure of the relationship between detailing and MMEs, did you?
MR. SOBOL: Objection.
A. Having run Model C and comparing the results to Model B, I deemed that it would not be fruitful to add further dummy variables and run a more expansive version of Model C.
BY MR. METZ:
Q. Do you agree that as a general matter in regression analysis failure to include a major explanatory variable that is correlated with the variable of interest in the regression model may cause an included variable to be credited within an effect that actually is caused by the excluded variable?
A. As we discussed earlier today, that notion which you just describe of omitted variable bias is a factor in any analysis, and there are constraints on how many variables one can include in an analysis.
So while it's always going to be true that there is a possibility of

Page 802

omitted variable bias, it's my opinion that including more of these event variables in the model would not improve the performance of the model.

Q. You mentioned the word "constraint" in that answer. And in previous testimony you've mentioned a term called "degrees of freedom."

A. Yes.

Q. Can you explain what degrees of freedom are as related to a constraint on the number of variables that can be included in a model?

A. It has to do with the number of observations and the number of included variables. It also has to do with the correlation in these data, so as we add more and more dummy variables, the chances that we get colinearity are higher.

Q. And degree of freedom refers in part to a point beyond which there's insufficient data to account for the number of permutations that more and more variables will introduce into the model; is that fair?

A. In effect, it makes it

Page 803

impossible to estimate the model.

Q. Okay. Did you have adequate data to add additional dummy variables beyond the five you included without running into the limit imposed by however many degrees of freedom you had?

MR. SOBOL: Objection, assumes a fact not in evidence.

A. I have adequate data in terms of degrees of freedom. In terms of concerns about adding more dummy variables and having them be correlated with one another to the point where I'm getting results like the ones I can see in Model C, where the coefficients are clearly picking up something different, that is the concern.

BY MR. METZ:

Q. So if I understand, your concern is that had you inquired further, you might have found nonsensical results?

MR. SOBOL: Objection, mischaracterizes the testimony.

A. My concern is that adding dummy variables would likely just make the other dummy variables nonsensical, whereas Model B

Page 804

compared to Model C, again, has qualitatively similar promotional effects that adding further dummy variables would simply interfere with the meaning of the dummy variables that are already in them. They would be impossible to differentiate.

BY MR. METZ:

Q. What's the basis for your statement that would likely be the consequence of adding additional dummy variables?

A. Just we talked before that these dummy variables are zero until they turn on and one after, and if we add one every six months, then we have a whole lot of vectors that are zero. You know, sort of in a staggered way, they're going to be highly correlated.

Q. And nonetheless, you did not test whether that would be the outcome of adding additional dummy variables or other explanatory variables, correct?

A. I did not consider adding other dummy variables.

Q. Okay. And there are

Page 805

conceivably other variables that are not dummy variables that one could add to test for the presence of additional factors, correct?

MR. SOBOL: Objection.

A. I include the standard factors that are included in an aggregate time series analysis of pharmaceutical promotion, which are -- I'm sorry, of pharmaceutical sales, which are promotion and price.

BY MR. METZ:

Q. Okay. But there are -- in any regression, one of the tasks is to hypothesize as to other conduct that could affect the variable of interest, and where available, to include data that would capture that conduct, correct?

MR. SOBOL: Objection, asked and answered.

A. Starting with the theory of demand for pharmaceuticals, I've constructed this model, including the most important variables, and again, one does not -- a well-constructed model focuses on the most important variables.

Page 806

This model using price and promotion is the same as models that I have used in similar instances, and it's very similar to the models in Berndt, except that those are at product level, but they also focus on price and promotion.

So in a time series context, there aren't a lot of other variables that you could even imagine would be included, and in my opinion, price and promotion are the key variables here.

BY MR. METZ:

Q. Did you spend any significant time in contemplative thought trying to imagine additional variables to include in your model beyond the ones you included?

MR. SOBOL: Objection, asked and answered.

A. I've spent 300 hours in developing the analyses that are in my report. I spent considerable time thinking about this model, and it wasn't the first time that I had thought about such analyses, as you know.

///

Page 807

BY MR. METZ:

Q. Now, did you -- within those 300 hours, did you spend any significant time seeking to identify the key events that should be attempted to be replicated with the dummy variables you ended up using?

MR. SOBOL: Objection, asked and answered.

A. Yes, you can see in my report that I culled those events again from various sources.

BY MR. METZ:

Q. Yes, and when I asked you about it, the answer you gave to me was that you looked at the expert report of Dr. Perri.

A. Yes.

Q. You looked at the plaintiffs' complaint.

A. Yes.

Q. And you looked at one timeline on the website, I believe of the FDA?

A. The FDA timeline. Those are the primary sources, yes.

Q. Okay. Now, did you see Dr. Perri's report significantly before your own report was finalized?

Page 808

A. I don't know what you mean by significantly.

Q. Well, in time to adequately evaluate whether the events described there were the key events you should be attempting to model for?

A. Yes, I did.

Q. How many days in advance?

MR. SOBOL: Objection.

A. I can't say. I can't say for sure when I saw that, but I obtained the information from Dr. Perri's report as I was putting together my model.

BY MR. METZ:

Q. Okay. Was it time adequate that when you ran your Model C and two of the dummy variables came back individually significant and the five collectively came back significant, did you then have time to consider and design and implement and still disclose on time another model with better dummy variables?

A. The --

MR. SOBOL: Objection to "better."

A. Time was not the issue here. I decided not to run a model with more dummy variables.

BY MR. METZ:

Q. Okay. I'm going to hand you what we're marking as Exhibit 29.

(Whereupon, Deposition Exhibit Rosenthal-29, Joint Statement, Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act, was marked for identification.)

BY MR. METZ:

Q. Have you seen Exhibit 29 previously?

A. I believe so, yes.

Q. What is it?

A. I'm actually looking for the date on it. Does it have a date?

Q. Well, I can represent to you that the particular version you're holding was pulled from an Internet archive that dates it as of a date that it was on the Internet, which may not be the first date it

Page 809

Page 810

was on the Internet.
A. I see.
Q. And in the top right corner it dates it as November 27, 2001.
A. I think is the -- it's the joint statement on promoting pain relief and preventing abuse of pain medications, but, sorry, what date did you think it was actually from?
Q. Well, the date that this particular copy is from --
A. Right.
Q. -- is November of 2001.
A. So it came out sometime before that.
Q. The date it was pulled on the Internet. I can't represent to you what date exactly it was, although I believe it to be a somewhat consistent time to what's reflected here, but I can't represent that to you.
A. Yes, I'm not sure if I have seen this specific document.
Q. Okay. And do you believe in looking at your Figure 5 that this is one of the event -- the key events dated on your

Page 811

timeline?
A. I'd have to look.
MR. SOBOL: Objection.
A. I just need to go back and find --
BY MR. METZ:
Q. I think Figure 5 is on page 41.
A. Thank you. I must have blown past it.
I don't believe that this is part of it. I was thinking of the consensus statement. But I think this joint statement is something different, but --
Q. Okay.
A. It's certainly labeled something different.
Q. So to your knowledge, you have not seen this previously; is that correct?
A. To my knowledge, no.
Q. All right. It's titled A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration.
Do you see that?
A. I do.
Q. And the title beneath that is

Page 812

Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.
Do you see that?
A. I do.
Q. Okay. And since you've not seen this before, I just want to read some of the included terms. It begins: As representatives of the healthcare community and law enforcement, we're working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need.
Do you see that?
A. Yes.
Q. And then skipping over a paragraph, the next one down, it says: Preventing drug abuse is an important societal goal, but there is consensus by law enforcement agencies, healthcare practitioners and patient advocates alike that it should not hinder patients' ability to receive the care they need and deserve.
Do you see that?
A. I do.
Q. And then it says: This

Page 813

consensus statement is necessary based on the following facts.
First bullet: Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care and pain should be treated aggressively.
Do you see that?
A. I do.
Q. And then the next bullet says: For many patients, opioid analgesics, when used as recommended by established pain management guidelines, are the most effective way to treat their pain and often the only treatment option that provides significant relief.
Do you see that?
A. I do.
Q. And would you agree with me that shares some of the characteristics of the statement you testified about earlier as well as yesterday, the joint statement?

Page 814

MR. SOBOL: Objection, beyond the scope.
A. Are you referring to --
MR. METZ: Beyond the scope of what?
MR. SOBOL: Beyond the scope of her opinions. You've got a document.
MR. METZ: That's the point.
MR. SOBOL: You've got a document before her that she says she hasn't seen before.
MR. METZ: Okay. Thank you.
MR. SOBOL: And you're asking her then to, so far, just read it with you, and now you've asked her to compare a document that she hasn't seen to a document that is referenced in her report, right? So that's beyond the scope of her opinion.
BY MR. METZ:
Q. Would you agree with me that this document and the portions I just read in particular share some of the characteristics that you identified about the joint statement that you testified about earlier today in

Page 815

answer to my questions as well as yesterday?
MR. SOBOL: Objection, form and beyond the scope.
A. Yesterday and today we talked about the American Academy of Pain Management and American Pain Society consensus statement, and how it describes pain as being undertreated and the utility of opioid treatment.
So in that sense, I can read here that this statement also describes pain as undertreated and opioid analgesics as an effective treatment.
BY MR. METZ:
Q. And we discussed as well the -- at least the potential that the reputations of the bodies making those statements would be part of what made that -- a statement like that significant.
Do you recall discussing that with me?
MR. SOBOL: Objection. Is the question -- no --
MR. METZ: The question is if she recalls the testimony.

Page 816

MR. SOBOL: Okay. So objection, mischaracterizes her prior testimony, and form.
A. I recall the discussion where I said that I believed one of the reasons that pharmaceutical manufacturers might seek to influence such statements is because the reputation of professional societies may legitimize their activity.
BY MR. METZ:
Q. Okay. And you would agree with that the -- as a general matter, the Drug Enforcement Administration is a reputable organization on matters pertaining to the legitimate use of controlled substances?
MR. SOBOL: Objection, scope of her opinion.
A. I understand that the Drug Enforcement Administration is the federal agency responsible for enforcing laws that pertain to controlled substances. I don't know -- I guess I don't know "reputable." I'm not an expert on the DEA. I don't really know its reputation. I certainly know what its function is.

Page 817

BY MR. METZ:
Q. You think the DEA might be disreputable on the subject of legitimate uses of controlled substances?
MR. SOBOL: Objection, scope, form.
A. I'm just saying I don't know the DEA's reputation. I know its purpose is to regulate controlled substances.
BY MR. METZ:
Q. As an economist forming hypotheses --
MR. SOBOL: Wait a second. Are you done with this exhibit?
MR. METZ: I haven't marked a new one. Is there a reason for interrupting me?
MR. SOBOL: Yes. I want to know if you were done with this exhibit.
MR. METZ: For what purpose? If you want -- I've set mine aside. If you'd like to set yours aside, set it aside, but I don't see the purpose for interrupting me.

Page 818

MR. SOBOL: Okay. You've asked to set it aside. I move to strike all the questions regarding the exhibit because they do not relate to the report and she has not seen the exhibit before.

MR. METZ: Well --

MR. SOBOL: Go ahead.

MR. METZ: -- that's the point in cross-examining an expert on the sufficiency of her inquiry is to test her on things that she might not have inquired about or seen, perhaps because Dr. Perri didn't flag them for her.

BY MR. METZ:

Q. The question I was going to ask you is: An economist, hypothesizing the key events that might be causally related to the sale of MMEs, and bearing in mind that you previously said a statement like this from a private organization would be sufficient to at least form a hypothesis, would you not hypothesize that the DEA among 28 other health organizations recognizing the

Page 819

undertreatment of pain and the potential for opioids to treat, not just pain generally but also chronic pain, could potentially have had an impact on MME sales?

MR. SOBOL: Objection.

BY MR. METZ:

Q. Is that a reasonable hypothesis for an economist in your position undertaking a study like this?

MR. SOBOL: Objection, form, compound.

A. A statement like this, like the statements I do cite in my report, may have had an effect on sales, and because there were many such statements happening, I use the differential promotional effectiveness over time to capture these broader effects across a larger number of factors.

I believe something like this, if it were widely disseminated -- I don't really know how widely disseminated this was -- may have had an effect, and therefore, that would be captured in my promotional effectiveness.

///

Page 820

BY MR. METZ:

Q. Well, that's the hypothesis described in paragraph 73 that Model C was intended to test, correct?

MR. SOBOL: Objection, misrepresent -- mischaracterizes the testimony.

A. My hypothesis is that these events early and late affected promotional effectiveness. Model C is a particular way of testing them, which has the limitations of involving a large number of dummy variables.

I conclude that those dummy variables do not qualitatively affect my results, and we can go back to that discussion if you want, but that was my conclusion.

BY MR. METZ:

Q. Yeah.

A. And that, in fact, the differential promotional effectiveness over time is picking up the influence of these environmental factors.

Q. Okay. Only because I'm short on time I'll ask it this way.

Page 821

You described in paragraph 73 of your report a hypothesis about the need to explicitly include control for these kinds of events as being the purpose of the robustness test in paragraph 73.

That's what you -- or the robustness test in Model C, excuse me. That's what you say in paragraph 73, correct?

MR. SOBOL: Objection. Objection to the form.

A. In paragraph 73, I say, in the middle of the first sentence: I tested the robustness of Model B by examining whether indicators of specific events and policies should be explicitly included in my model.

BY MR. METZ:

Q. Thank you.

And in Model C, where you included dummy variables, you included three dummy variables that turned on --

A. Yes.

Q. -- prior to -- prior to November of 2001, correct?

A. That's correct.

Q. And the most proximate in time

Page 822

of those turned on -- was it in January of 2001 or does it turn on in February? I wasn't clear from the way you described in your model.

A. I need to look in the errata, because I think what was stated in the report was different in two different places.

Q. Okay.

A. So let me just take a quick look.

Q. For purposes of my question this will be sufficient.

A. Okay.

Q. It's either/or January or February, correct? If the dummy variable is dated January 2001.

A. I believe that that is true. I just didn't want to misstate it. You're talking about the JCAHO pain standards.

Q. Yes.

A. Yes.

Q. Okay. And then if this statement, in fact, was released in November of 2001, that is ten months after your dummy variable had already turned on, correct?

Page 823

A. That's correct.

Q. And then you do not have another dummy variable that you include until August of 2010, which is close to nine years later.

A. Yes. And because the dummy variable stays on, it will pick up any level shift over time after that, controlling for other factors, right.

Q. Any level shift that in the calculation shows up is correlated with the dummy variable from nine months earlier, correct?

A. Yes, but again, the dummy variable stays on over the period when this would have been released.

Q. Does not the distance from the dummy variable have a bearing upon the significance that that variable will attach to events later in time?

A. Well, again, it is literally picking up an average shift before compared to after.

Q. Okay. And if there are other unexplained events going on, you might

Page 824

attribute those to dummy variables that are years apart from when you first turned them on, correct?

MR. SOBOL: Objection.

A. This is why I conclude that Model B is the more appropriate approach here, to not try to disentangle those things.

BY MR. METZ:

Q. Okay. But in the ideal design of your model, as you told me before, you picked the timing of the dummy variable to coincide with the key events, not to have them be months prior so that they'll just sweep them up eventually, correct?

MR. SOBOL: Objection, form.

A. The dummy variables are intended to reflect the timing of these key events? Yes.

BY MR. METZ:

Q. The -- any dummy variable, the timing for when you turn it on, is intended to be timing that makes sense in light of the key events you're testing for, right?

A. It does. I'm just saying that just mathematically, the case that while that

Page 825

timing is important, it's important because it differentiates pre from post. It doesn't -- it's not instantaneous.

Q. Okay. And nonetheless, you put your variable in January 2001 in order to attempt to simulate for an event occurring in or around January 2001, correct?

MR. SOBOL: Objection, asked and answered.

A. Yes.

(Whereupon, Deposition Exhibit Rosenthal-30, State of Ohio House Bill No. 187, was marked for identification.)

BY MR. METZ:

Q. I'm going to hand you an exhibit we've marked Exhibit 30. I'd like you to take a look at that and tell me if you've seen it before.

A. I just want to check my documents relied upon. My memory is not always reliable.

(Document review.)

A. I don't think that I've seen this document before.

Page 826

BY MR. METZ:
Q. Well, in that case, Exhibit 30 is a printout from a legal -- well, from a book of Ohio session laws, and it's entitled H.B. No. 187, and in the title it says Treatment of Intractable Pain.
Do you see that?
A. I do see that.
Q. Okay. It's described as an act regarding the authority of physicians to prescribe, dispense and administer dangerous drugs for management of intractable pain.
Do you see that?
A. I see that.
Q. And under the first -- when you look into the body of the bill, next to number 2 it defines intractable pain.
Do you see that?
A. Yes.
Q. And it means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.

Page 827

Do you see that?
A. Yes.
Q. And then if you skip down to (C), the bill states that when a physician diagnoses an individual as having intractable pain, the physician may treat the pain by managing it with dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions.
Do you see that?
A. I do.
Q. Do you understand intractable pain as so described here to have a similar meaning to chronic pain?
MR. SOBOL: Objection, scope.
A. I do not, no.
BY MR. METZ:
Q. Okay. Do you understand it to be describing pain for which -- pain that will endure over a longer period because there is no -- no other means of curing it?
MR. SOBOL: Objection, scope.
A. Well, I'm not a clinical expert. It seems to define it as having no treatment or cure. It does not say anything

Page 828

about the longevity of the pain.
BY MR. METZ:
Q. Okay. And then if you flip ahead to subpart (D), which is on the second page, it states that a physician who treats intractable pain by managing it with dangerous drugs is not subject to disciplinary action by the board under Section 4731.22 of the revised code, solely because the physician treated the intractable pain with dangerous drugs.
The physician is subject to disciplinary action only if the dangerous drugs are not prescribed, administered or dispensed in accordance with this section and the rules adopted under it.
Do you see that?
A. I do.
Q. And were you aware prior to this moment of a law that was passed in Ohio in the late 1990s that provided doctors with legal protection for -- against circumstances in which they treated patients with pain using dangerous drugs? Were you aware of such a law being passed?

Page 829

MR. SOBOL: Objection, form.
A. I couldn't have told you when such a law was passed in Ohio.
I was aware from the complaint and from Dr. Perri's report that the influence -- the industry allegedly influenced such guidelines, including, as I include in my timeline, the model guidelines supplied by the Federation of State Medical Boards, and I take this to be an example of one that was implemented in Ohio.
BY MR. METZ:
Q. So is it your understanding that a state medical board guideline and a Ohio statute passed by the legislature of Ohio to be functionally equivalent? Is that what your answer was?
MR. SOBOL: Objection, mischaracterizes her testimony.
MR. METZ: That's why I'm asking for clarification.
A. I'm not a lawyer or a state regulatory expert. These guidelines that I'm seeing for the first time reading them, they are consistent with what I understand the

Page 830

goal of the Federation for State Medical Board Model Guidelines were, this protection from liability.
BY MR. METZ:
Q. They're consistent in their goals; they're inconsistent that -- in the sense that in this instance, pertaining to Ohio, it's being adopted by the 122nd Elected General Assembly of the State of Ohio.
Do you see that?
MR. SOBOL: Objection. Oh, just do you see that? That's fine.
A. I do.
BY MR. METZ:
Q. Okay. And do you agree with me that there is a difference between a private or a standard-setting unelected body creating some rule or regulation and the elected assembly of a state like Ohio enacting a law?
MR. SOBOL: Objection to the scope.
BY MR. METZ:
Q. Do you see a difference between those two things?
MR. SOBOL: Objection to scope.

Page 831

A. I'm not a legal or regulatory expert, so I don't have an opinion about the different effects of those two things.
BY MR. METZ:
Q. Okay. To be clear, I wasn't asking about effects. I was asking about the nature of the body adopting them.
Do you see a difference in the nature of the body adopting what you've described as guidelines versus the Assembly of Ohio adopting a law?
MR. SOBOL: Objection, asked and answered.
A. I understand that -- again, I understand that this is a law, and I believe the model guidelines were intended to influence regulations. I understand the difference between those two things.
BY MR. METZ:
Q. Okay. Thank you.
Now, this also does not appear on your timeline of key events, correct?
A. It does not.
Q. Okay. And you did not design a dummy variable with the specific intention of

Page 832

trying to capture any effects from this law, correct?
A. I did not.
Q. Okay. And, in fact, although your testimony is being used solely for purposes of this case, within two counties in Ohio, your aggregate analysis is done on a national level, correct?
MR. SOBOL: Objection, asked and answered.
A. My analysis is a national aggregate analysis.
BY MR. METZ:
Q. And one consequence of doing a national aggregate analysis is that if a law like this had an impact within the state of Ohio, that effect might be muted in your national analysis because there's 49 other states, right?
MR. SOBOL: Objection, form.
A. The national analysis will be affected by the extent of such laws across the country, not on just one state.
BY MR. METZ:
Q. And if Ohio was

Page 833

disproportionately affected by a law such as this, that effect might be different from the average that's reflected in your national aggregate analysis, correct?
MR. SOBOL: Objection, form.
A. That may be the case. As I understand this law, it seems to be that it would cause even more prescribing than I estimate on average, if other states lag Ohio.
BY MR. METZ:
Q. Okay. Even more within Ohio is what you're saying?
A. Even more than I attribute to Ohio, yes.
Q. Okay. Now, that law was not identified for you by Dr. Perri as one of the key events as it related to your opinions for Cuyahoga and Summit Counties, correct?
A. Just to be clear, Dr. Perri wasn't identifying for me. I understand the events that he described in his reports, that he identifies as part of his report as being important.
Q. And in part because this was

Page 834

not described in that report and because it is not reflected in plaintiffs' complaint, it's not one of the key events that you put into your Figure 5, correct?

MR. SOBOL: Objection, mischaracterizes the testimony.

A. I do not believe it appears in the sources that I used to put together Figure 5.

BY MR. METZ:

Q. Okay.

A. So I did not rely on it.

Q. In the inquiry you independently undertook to identify what key events should be accounted for in your model, did you come across any information indicating that, in fact, this law had had an influence on MMEs within the state of Ohio such that it should be accounted for?

A. I am not aware of anything, no. I did not come across that.

(Whereupon, Deposition Exhibit Rosenthal-31, Ohio Prescription Drug Abuse Task Force Final Report, was marked for identification.)

Page 835

BY MR. METZ:

Q. I'm going to hand you an exhibit marked Exhibit 31.

MR. SOBOL: Where are we on the time?

MR. METZ: I think I have about 15 minutes.

THE VIDEOGRAPHER: 19.

MR. SOBOL: Thanks.

THE WITNESS: Go ahead.

BY MR. METZ:

Q. Have you seen this document before?

A. I don't think so. I should check again my documents cited.

(Document review.)

A. I assume it would be under O for Ohio.

BY MR. METZ:

Q. I haven't checked. It could also be under 2010. I don't know.

A. I don't think so.

Q. Okay. You don't recognize it as you sit here?

A. I don't.

Page 836

Q. Okay. I will represent to you that Exhibit 31 is a final report and task force recommendations from a body known as the Ohio Prescription Drug Abuse Task Force. Do you see that?

A. Yes.

Q. And in your inquiry and research into finding the key factors that you try to be accounted for in your model, did you at any point come to learn that Ohio had commissioned a drug abuse task force relating to the subject of prescription drugs?

A. I believe that I was aware that there had been activity in Ohio related to combatting the opioid epidemic.

Q. Okay. But you don't recall seeing any report or other information about that, do you?

A. I don't recall.

Q. Okay. Now, I want you to turn first to page 21, just so I can orient you to the section in which a later page appears.

A. Okay.

Q. Do you see that there's a

Page 837

heading there that says How Did This Become an Epidemic?

A. Yes, I do.

Q. And there's some information there followed by a chart, okay?

A. Yes.

Q. If you turn to the next page, the next -- the section at the top of page 22 talks about the law that we just considered, that we just looked at, and I'll just read it into the record.

Under the heading Changes in Clinical Pain Management, the document states: Growing recognition by professionals of the undertreatment of pain in the late 1990s prompted needed changes in clinical pain management guidelines at the national level, as well as changes in Ohio's law regarding the treatment of intractable pain. As defined in Ohio law, intractable pain means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been

Page 838

found.
Do you see that?
A. Yes.
Q. And you recall that's the definition we read from the statute a moment ago, correct?
A. It looks like it's verbatim.
Q. Okay. So the next paragraph says: To address the perception that prescribing adequate amounts of controlled substances would result in unnecessary scrutiny by regulatory authorities, Ohio's Intractable Pain Act provided that physicians treating intractable pain are not subject to disciplinary action when practicing in accordance with accepted and prevailing standards of care and rules adopted by the medical board delineating those standards.
Do you see that?
A. Yes. And I guess now I see how the law connects to the state medical board standards. They're clearly interlocking.
Q. And then it says: Such fundamental changes in the recognition and treatment of pain contributed to increased

Page 839

prescribing and concomitant availability of and exposure to potent opioid analgesics, pain medications.
Do you see that?
A. I do.
Q. Okay. So prior to now, were you aware that an appointed task force appointed by the government of the State of Ohio had, in a report, concluded that the law we looked at a moment ago from 1997 had contributed to the levels of prescription opioids dispensed in Ohio during the period covered by your study?
MR. SOBOL: Objection, form, asked and answered.
A. I wasn't aware of this specific report. Again, going back to the context of Dr. Perri's report and what I understand the allegations are in this matter, it does not come as a surprise to me that this was found. And again, this explicitly references those state medical board guidelines.
Those, as I understand it, plaintiffs intend to prove were a vehicle for increasing -- basically opening the flood

Page 840

gates for opioid prescribing. So this simply confirms that the State of Ohio has found that to be true.
BY MR. METZ:
Q. And you did not include in your model a variable intended to capture, for sales within Ohio, the influences of the statute, correct?
MR. SOBOL: Objection, asked and answered.
MR. METZ: It's really a yes-or-no question.
MR. SOBOL: Well, you can answer it however you think you need to.
A. I included in my model national variables. And as I've noted, I believe factors such as these are why promotion was so effective in that early part of the period that I analyze.
In my view, it would not be appropriate to try to pull out this effect when it is all part of how promotion caused sales.
///

Page 841

BY MR. METZ:
Q. Well, in your view in -- as expressed in paragraph 73, it was necessary as a robustness test to test the very assumption you just stated to me as to whether these events, events like this, had a sufficiently strong influence to render Model B inaccurate.
MR. SOBOL: Objection.
BY MR. METZ:
Q. Isn't that what you said in your report?
MR. SOBOL: Objection, asked and answered already.
A. As I said in my report, I'm testing the form of the model. I do not -- I do not use Model C in calculating damages, but it is not my belief that those variables necessarily would occur in a but-for scenario.
And so Model C, the robustness check is around the specification, and while I understand that you respectfully disagree, I conclude that, in fact, Model C supports the use of Model B. But even if there were a

Page 842

significant dummy variable in Model C, it wouldn't necessarily be the case that that variable would exist in the but-for world.
BY MR. METZ:
Q. Okay. So to -- if I could strip that down to a more relatable statement.
You're postulating a but-for world in which the State of Ohio's General Assembly does not enact the statute that we just looked at?
MR. SOBOL: Objection, mischaracterizes her testimony.
A. I don't know about the specific law, but many of those events, including the state medical board guidelines, which appear to interact with the law, are posited by plaintiffs to have been caused by the conduct of defendants.
MR. METZ: Why don't we go off the record.
THE VIDEOGRAPHER: The time is 3:26 p.m. We're now off the record.
(Recess taken, 3:26 p.m. to 3:33 p.m.)

Page 843

THE VIDEOGRAPHER: The time is 3:33 p.m. We're back on the record.
EXAMINATION
BY MR. GEISE:
Q. Professor Rosenthal, my name is Steve Geise. I represent Walmart in this case. We had a chance to meet off the record and I just have a very few questions for you today because our time is running to a close.
In response to questions from Mr. Metz, you indicated you had not analyzed pharmacy conduct at all for purposes of your opinions; is that correct?
MR. SOBOL: Objection, asked and answered.
A. Yes, I do not analyze pharmacy conduct in my analysis.
BY MR. GEISE:
Q. Yesterday in response to a question, you testified that distributors' conduct was outside the scope of your report. Is it true that retail pharmacy conduct is also outside the scope of your report?
MR. SOBOL: Objection.
A. My analysis does not include

Page 844

retail pharmacy conduct.
BY MR. GEISE:
Q. The assignment that you were given by plaintiffs' counsel did not include considering any conduct by a retail pharmacy defendant, correct?
A. My assignment pertains to the marketing conduct and not to the conduct of retail pharmacies.
Q. If you look at Exhibit 1 to your deposition, which is your expert report, in particular, your Figure 1 on page 19, this is your promotion ecosystem, correct?
A. Yes.
Q. You would agree that retail pharmacy defendants are not part of that promotion ecosystem at all, correct?
A. Retail pharmacies are not part of the promotion ecosystem that I describe here.
MR. GEISE: Thank you. Those are my questions.
THE VIDEOGRAPHER: The time is 3:34 p.m. We're off the record.
(Recess taken, 3:34 p.m. to

Page 845

3:35 p.m.)
THE VIDEOGRAPHER: The time is 3:35 p.m. We're back on the record.
EXAMINATION
BY MR. SOBOL:
Q. You were asked some questions yesterday and today about the assignment that you were given. The assignment you were given was with respect to modeling the combined effect of certain manufacturer defendants' marketing, correct?
A. Yes, that's correct.
Q. The lawyers, though, didn't tell you what type of model you should use, correct?
A. That's correct.
Q. You chose the aggregate model, correct?
A. I chose the aggregate model to estimate aggregate impact, as I have described over the last day and a half, because the aggregate model allows me to capture spillover effects and is the most efficient way to estimate the combined effect of defendants' alleged marketing misconduct.

MR. SOBOL: Nothing further.
MR. ROTH: No follow-up here.
THE VIDEOGRAPHER: That concludes the deposition of Meredith Rosenthal. The time is 3:36 p.m., and we're now off the record.
(Proceedings recessed at 3:36 p.m.)
--o0o--

CERTIFICATE

I, MICHAEL E. MILLER, Fellow of the Academy of Professional Reporters, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that prior to the commencement of the examination, MEREDITH B. ROSENTHAL, Ph.D. was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that pursuant to FRCP Rule 30, signature of the witness was not requested by the witness or other party before the conclusion of the deposition.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____
MICHAEL E. MILLER, FAPR, RDR, CRR
Fellow of the Academy of Professional Reporters
NCRA Registered Diplomate Reporter
NCRA Certified Realtime Reporter
Certified Court Reporter

Notary Public
My Commission Expires: 7/9/2020
Dated: May 6, 2019

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

PAGE LINE CHANGE
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________
____ ____ ____________________
REASON: ____________________

ACKNOWLEDGMENT OF DEPONENT

I, MEREDITH B. ROSENTHAL, Ph.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
MEREDITH B. ROSENTHAL, Ph.D. DATE

Subscribed and sworn to before me this
_______ day of ______________, 20 _____.
My commission expires: _______________

____
Notary Public

LAWYER'S NOTES

PAGE LINE

PAGE	LINE	
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________
____	____	____________________________